466. Dr. Fishman said that he did not receive any payments from FSMB or any royalties from the publisher because he wanted to avoid the perception of a potential conflict of interest in his authorship of the book or for the ongoing efforts of FSMB. This is because prior to 2011, he had been scrutinized for his involvement with the front groups/manufacturers and accepting payments.[177]

467. The Manufacturing Defendants made additional contributions to the FSMB to further their misleading advertising. For example, Purdue paid FSMB $822,400.06 over 8 years.[178] Cephalon paid FSMB $180,000 over 3-year period 2007-2008 and 2011.[179] Endo paid FSMB $371,620 over a 5 year period.[180] Mallinckrodt paid FSMB $100,000 in 2011.[181]

4. The Alliance for Patient Access

468. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[182] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[183] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes J&J, Endo, Mallinckrodt, Purdue and Cephalon.

---

[177] Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf.
[178] Letter from Humayun J. Chaudhry, President and CEO, FSMB, to the Hon. Max Baucus and Hon. Charles Grassley, U.S. Senate (June 8, 2012), https://www.documentcloud.org/documents/3109089-FSMB-Response-Letter-to-US-Senate.html.
[179] *Id.*
[180] *Id.*
[181] *Id.*
[182] The Alliance for Patient Access, *About AfPA*, http://allianceforpatientaccess.org/about-afpa/#membership (last accessed August 1, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.
[183] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017),

469. APA's board members have also directly received substantial funding from pharmaceutical companies.[184] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from defendants Endo, Purdue and Cephalon, and nonparty Insys. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[185] Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Mallinckrodt and Cephalon and nonparty Insys; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

470. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[186] Among other things, the white

---

https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ ("Jaklevic, *Non-profit Alliance for Patient Access*").

[184] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, *available at* https://projects.propublica.org/docdollars/.

[185] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, KANSAS CITY STAR (July 19, 2017), http://www.kansascity.com/news/business/health-care/article162569383.html.

[186] Institute for Patient Access, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/01/PT_White-Paper_Finala.pdf.

paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> ***
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .
>
> We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[187]

471. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[188]

[187] *Id.* at 4-5 (footnote omitted).
[188] *Id.* at 5-6.

472. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.[189]

473. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[190]

474. The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they were generally given to members of Congress who supported the APA's agenda.[191]

475. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing

---

[189] *Id.* at 6.
[190] *Id.* at 7.
[191] Jaklevic, *Non-profit Alliance for Patient Access*, *supra* n. 183.

the "suspicious orders" provision of the CSA.[192] The AAPM is also a signatory to this letter. An internal DOJ memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'"[193] and, according to DEA chief administrative law judge John J. Mulrooney, the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like Defendants here, in the courts.[194] The law passed both Houses of Congress and was signed into law in 2016.

5. The U.S. Pain Foundation

476. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone.[195] The USPF was also a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertised its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Assertio, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.[196] Industry Front Groups like the American Academy

---

[192] Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015).
[193] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS NEWS (last updated Oct. 17, 2017) https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ (hereinafter, "Whitaker, Opioid Crisis Fueled by Drug Industry").
[194] John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. (forthcoming Feb. 2018), https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html.
[195] *Fueling an Epidemic*, at p. 4.
[196] *Id.* at 12; U.S. Pain Foundation, *Transparency*, https://uspainfoundation.org/transparency/. (last accessed on August 1, 2018).
[196] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331 (2009), https://www.ncbi.nlm.nih.gov/pubmed/19573219 (last accessed on August 1, 2018).

of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

477. More specifically, Purdue paid $359,300 from 2012-2017.[197] Janssen paid $41,500 from 2012-2017;[198] and nonparty Insys paid $2,500,000 from 2012-2017 to the USPF.[199]

6. American Geriatrics Society

478. The AGS was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*,[200] hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009.[201] AGS's complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

---

[197] *Id.*
[198] *Id.*
[199] *Id.*
[200] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331 (2009), https://www.ncbi.nlm.nih.gov/pubmed/19573219 (last accessed on August 1, 2018).
[201] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), https://www.medpagetoday.com/geriatrics/painmanagement/32967.

479. More specifically, Purdue paid $11,785 from 2012-2017[202] and provided $40,000 in "corporate roundtable dues" to AGS's Health in Aging Foundation, a 501(c)(3) organization affiliated with the group between 2012 and 2015.[203]

480. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." The panel made "strong recommendations" in this regard despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse.[204] These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 500 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

481. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

---

[202] *Fueling an Epidemic Part Two.*
[203] Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).
[204] 2009 AGS Guidelines, at 1342.

482. Dr. Bruce Farrell was an AGS task force chairman for the 2009 Guidelines, but was also a paid speaker for Endo, and he helped conduct a CME for treating osteoarthritis pain, which was funded by Purdue.[205]

483. Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

484. Members of AGS Board of Directors were doctors who were on the Marketing Defendants' payrolls, either as consultants or as speakers for medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

7. American Chronic Pain Association

485. The Manufacturer Defendants also made substantial payments to the American Chronic Pain Association ("ACPA"). Founded in 1980, the ACPA offers support and education for people suffering with chronic pain.

486. Contributions to the ACPA from the Manufacturing Defendants include $312,470 from Purdue and $50,000 from Janssen from 2012-2017.[206] Between 2013 and 2016, 10 members of ACPA's Advisory Board received more than $140,000 from opioid manufacturers, including Endo.

C. The Marketing Defendants Deceptively Paid KOLs to Promote Opioid Use

487. To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their

[205] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), https://www.medpagetoday.com/geriatrics/painmanagement/32967.
[206] *Fueling an Epidemic Part Two*.

supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception that science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine and Dr. Scott Fishman.

488. Although these KOLs were funded by the Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

489. As the Marketing Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that developed, selected, and presented CMEs.

490. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of each of these modalities through which doctors receive their information.

491. In return for their pro-opioid advocacy, the Marketing Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

492. The Marketing Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' agenda. The Marketing Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Marketing Defendants also kept these KOLs well-funded enabling them to push the Marketing Defendants' deceptive message out to the medical community.

493. Once the Marketing Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Marketing Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescriptions of opioids for chronic pain. The Marketing Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

494. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants.

1. Dr. Russell Portenoy

495. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew

substantial gains in employment or social function could be attributed to the institution of opioid therapy."[207]

496. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

> *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[208]

(emphasis added). According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[209]

497. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians

---

[207] Russell Portenoy & Kathy Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986), https://www.ncbi.nlm.nih.gov/pubmed/2873550.
[208] Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).
[209] *Id.*

for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'"[210]

498. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified."[211]

499. Dr. Portenoy was also a critical component of the Marketing Defendants' control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

500. In recent years, some of the Marketing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.[212] Dr. Portenoy has now admitted that he minimized the risks of opioids,[213] and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[214] He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ."[215]

---

[210] *Dreamland* at 314.
[211] *Id.* at 136.
[212] *See, e.g.*, John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/ (reporting that a key Endo KOL acknowledged that opioid marketing went too far).
[213] Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, THE NEW YORKER (Nov. 8, 2013), https://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic (hereinafter "Gounder, *Who Is Responsible*").
[214] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012, 11:36am), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[215] *Id.*

501. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*[216]

502. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."[217]

2. Dr. Lynn Webster

503. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of Pain Medicine, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

---

[216] Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER (May 26, 2016), http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be.

[217] *Pain Killer*, *supra* n. 94, at 277.

504. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool ("ORT") appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors at hospitals such as Plaintiffs.

505. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

506. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study

suggest that [fentanyl buccal] is safe and well-tolerated in patients with chronic pain and [breakthrough pain]." This CME effectively amounted to off-label promotion of Cephalon's opioids, even though they were approved only for cancer pain.

507. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

3. Dr. Perry Fine

508. Dr. Perry Fine's ties to the Marketing Defendants have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.[218]

509. Multiple videos feature Dr. Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith before her death for pain did not make her an addict.

---

[218] Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true.

510. Dr. Fine has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under $5,000 in 2010 from Johnson & Johnson for providing "educational" services, but Johnson & Johnson's website states that the company paid him $32,017 that year for consulting, promotional talks, meals and travel.[219]

511. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

> At clinically appropriate doses . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.
>
> Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.[220]

512. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[221] In that article, Dr. Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP

---

[219] Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry.

[220] Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), http://www.thblack.com/links/RSD/OpioidHandbook.pdf.

[221] Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for non-cancer pain."[222] The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic non-cancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[223]

513. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small."[224]

514. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but also for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain.[225] He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*."[226] The entire program assumes that opioids are an appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to

---

[222] *Id.*
[223] *Id.*
[224] *Id.*
[225] Perry A. Fine, M.D., *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI
[226] *Id.*

treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[227]

4. Dr. Scott Fishman

515. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[228]

516. Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing," in 2007 which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

517. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce

---

[227] *Id.*

[228] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (hereinafter "Weber, *Two Leaders in Pain*").

> diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.[229]

518. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins."[230]

519. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."[231] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

D. The Marketing Defendants Also Spread Their Misleading Messages to Reputable Organizations

520. The Manufacturing Defendants also manipulated reputable organizations like the Joint Commission on Accreditation of Healthcare Organizations (the "Joint Commission") in order to further advance their unlawful marketing of opioids. The Joint Commission certifies over 21,000 health care organizations and is the nation's oldest and largest standards-setting and accrediting body in health care.[232]

521. In 2000, Purdue sponsored a book through the Joint Commission which claimed "there is no evidence that addiction is a significant issue when persons are given opioids for pain control."[233] It also called doctors' concerns about addiction side effects "inaccurate and

---

[229] Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).
[230] *Id.*
[231] Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).
[232] Joint Commission, *FAQ Page*, *available at* https://www.jointcommission.org/about/jointcommissionfaqs.aspx?CategoryId=10#2274 (last accessed August 1, 2018).
[233] Sonia Moghe, *Opioid history: From 'wonder drug' to abuse epidemic*, CNN (Oct. 13, 2016), https://www.cnn.com/2016/05/12/health/opioid-addiction-history/.

exaggerated."[234] Dr. David W. Baker, the Joint Commission's executive vice president for health care quality evaluation, has acknowledged that "The Joint Commission was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information."[235]

522. In 2001, due to the influence of the Marketing Defendants, the Joint Commission, along with the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies[236]) "introduced standards for [hospitals] to improve their care for patients with pain." The new standards for hospitals put patient pain front and center as the "fifth vital sign." This monograph, entitled *Pain: Current understanding of Assessment, Management and Treatments* required assessment of pain in all patients.

523. The Joint Commission's first pain management standards placed responsibility for pain control on health care organizations (hospitals); and, emphasized the need for hospitals to do systematic assessments and use quantitative measures of pain which was consistent with the position of the Front Group APS.

524. As a result of the Marketing Defendants' efforts to manipulate the standard of care, many hospitals, including Plaintiffs, risked loss of their Joint Commission accreditation if they did not incorporate the "fifth vital sign" standard and put pain at the forefront of their treatment. For example, the emergency department at Oconomowoc Memorial Hospital in Wisconsin achieved 10 consecutive years of patient satisfaction in the 99th percentile, a feat no other emergency hospital in the United States has been able to accomplish.[237] However, during its routine Joint Commission survey, The Joint Commission found that the hospital was not

---

[234] *Id.*
[235] *Id.*
[236] Currently funded by Johnson & Johnson, Purdue and Teva, among others.
[237] Westlake testimony, at 6.

adequately documenting follow up questions after prescribing pain medications to patients.[238] As a result, the hospital was given only one quarter to bring their compliance up to 90%.[239] They could not, and as a result their Joint Commission accreditation was at risk for the entire hospital.[240] Loss of accreditation by The Joint Commission can result in the loss of a huge amount of hospital resources to become reaccredited, despite having a patient satisfaction rating of 99% for the same period.[241]

525. Since 2001, The Joint Commission standards relating to pain assessment and management have been revised to lessen emphasis on pain. However, the damage caused by the Marketing Defendants' marketing campaigns could not be undone. Dr. Baker explains that "the concept that iatrogenic addiction was rare and that long acting opioids were less addictive had been greatly reinforced and widely repeated, and studies refuting these claims were not published until several years later."

E. The Marketing Defendants Disseminated Their Misrepresentations Through CME Programs

526. Now that the Marketing Defendants had both a group of physician promoters and had built a false body of "literature," Defendants needed to make sure their false marketing message was widely distributed.

527. One way the Marketing Defendants aggressively distributed their false message was through countless CME programs.

528. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are generally delivered in person,

---

[238] *Id.*
[239] *Id.*
[240] *Id.*
[241] *Id.*

often in connection with professional organizations' conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

529. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants' deceptions.

530. The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

531. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

532. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex

pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmaco therapeutics to affect multiple points in the pain-signaling pathway."[242] The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process.[243] Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

533. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

534. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Fishman.

535. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

536. The American Medical Association ("AMA") recognized the impropriety that pharmaceutical company-funded CMEs create, stating that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests

---

[242] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, http://www.medscape.org/viewarticle/461612 (last accessed August 1, 2018).
[243] *Id.*

could influence the availability and/or content" of the programs and urged that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[244]

537. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

538. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants expected and understood that instructors would deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Marketing Defendants both measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

F. The Marketing Defendants Used "Branded" Advertising to Promote Their Products to Doctors and Consumers

539. The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the Journal of Pain and Clinical Journal of Pain, to journals with wider medical audiences, such as the Journal of the American Medical Association. The Marketing Defendants collectively spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in

[244] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).

2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

540. The Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.[245] They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[246] Endo's research, for example, also found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

G. The Marketing Defendants Used "Unbranded" Advertising to Promote Opioid Use for Chronic Pain Without FDA Review

541. The Marketing Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the

[245] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).
[246] *Id.*

FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

542. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

H. The Marketing Defendants Funded, Edited and Distributed Publications That Supported Their Misrepresentations

543. The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was calculated to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

544. To accomplish their goal, the Marketing Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

545. The Marketing Defendants' plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other

area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Marketing Defendants' marketing departments.

546. The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

547. The Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

548. For example, in 2007, Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[247] published in the nationally circulated Journal of Pain Medicine, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Webster, discussed above) stated that the "OTFC [fentanyl] has been shown to relieve BTP [breakthrough pain] more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of non-cancer pain patients." The number-one-diagnosed cause of chronic pain in the

[247] Donald R. Taylor, et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).

patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

549. In summary, BTP appears to be a clinically important condition in patients with chronic non-cancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.[248]

I. The Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.

550. In addition to making sales calls, the Marketing Defendants' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers with meals paid for by the Marketing Defendants. These speaker programs and associated speaker trainings served three purposes: they provided 1) an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; 2) an opportunity for doctors to be selected to attend a forum at which the drug companies could further market to the speaker himself or herself; and 3) an opportunity for the doctors to market to their peers. The Marketing Defendants graded their speakers, and future opportunities were based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

[248] *Id.*

IV. The Marketing Defendants' Goal Was for More Patients to Take More Opioids at Higher Doses for Longer Periods of Time

A. Increasing the Patient Population

1. The Marketing Defendants Focused on Vulnerable Populations

551. The Marketing Defendants specifically targeted their marketing at two particularly vulnerable populations—the elderly and veterans – who tend to suffer from chronic pain.

552. Internal Purdue documents demonstrate that the Purdue Individual Defendants focused on elderly patients because they are frequent pain sufferers, and, of equal importance, are likely to be covered by Medicare. Purdue internal documents reflected that if it targeted "Patients over the age of 65 … more Medicare Part D coverage is achieved."

553. Elderly patients frequently suffer from osteoarthritis, but opioids are not approved to treat the condition. Purdue conducted a single study on osteoarthritis for its Butrans opioid, and it failed. Purdue admitted in internal documents that its opioids "are not indicated for a specific disease" and "it is very important that you never suggest to your HCP [health care professional] that OxyContin is indicated for the treatment of a specific disease state such as Rheumatoid Arthritis or Osteoarthritis." Nevertheless, to meet its business goals, Purdue trained its representatives to mislead doctors by promoting opioids for osteoarthritis without disclosing Purdue's failed trial. Purdue even measured how often it targeted osteoarthritis patients. A Purdue marketing presentation concluded that its sales reps were "identifying appropriate patients" because osteoarthritis was specifically mentioned during 35% of sales visits. Purdue also directed sales reps to use marketing materials that highlight patients with osteoarthritis, even though Purdue drugs were never indicated for that disease and Purdue's Butrans trial had failed. At one point, the Purdue Individual Defendants wanted to know if sales reps could sell more by

remaining silent about the failed trial: "What can be said in response to a prescriber who asks directly or indirectly, 'can this product be prescribed for my patient with OA?' In responding are we required to specifically mention the failed trials in OA?"

554. The Marketing Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, a 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.[249] Elderly patients taking opioids have also been found to have a greater risk for hospitalizations and increased vulnerability to adverse drug effects and interactions, such as respiratory depression. The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.[250]

2. The Marketing Defendants Focused on Having Opioids Perceived as a "First Line" of Medication for "Opioid-Naïve" Patients, Rather Than as a Last Resort for Cancer Patients and the Terminally Ill

555. From the very beginning, Purdue and Abbott intended to position OxyContin as useful for more than just cancer pain. Internal documents from the 1995 "OxyContin Launch" indicate that they also intended it for a "secondary market . . . for non-malignant pain (musculoskeletal, injury and trauma)" and that it must be "reinforced that we do not want to niche OxyContin just for cancer pain."

556. In 1996, Purdue envisioned OxyContin being prescribed for a long laundry list of conditions, and literally generated a "wish list" of clinical studies to support its prescription in a variety of contexts, including: (1) postoperative pain, with specific objectives of supporting the

[249] Dowell, CDC Guideline, *supra* n. 23.
[250] *Id.* at 27.

"Abbott agreement" to market to hospitals, removing "the prohibition of giving the product during the 12-24 hour immediate postop period," and removing "the qualification limiting the indication to pain for more than a few days;" (2) "nonmalignant pain" (including low back pain, osteoarthritis); and (3) HIV/AIDS treatment.

557. Purdue, particularly after its overall OxyContin sales began to slow after 2010, instructed its sales representatives to focus on expanding the patient base, by promoting its drugs specifically for patients who had not previously taken opioids, who it described as "opioid-naïve" or simply "naïve" patients:

- *"Your opportunity here is with the naïve community, let's use the naïve trial to make your case."*
- *"You created an epiphany with the doctor today (potentially) by reviewing the opiate naïve patient profile. What made him more pat to write for this patient, being an amiable doctor, is the fact that he would not have to talk patients out of their short acting [opioids]."*
- *"This was an example of what a good call looks like ... [Dr.] was particularly interested in the RM case study of Marjorie, which generated a robust discussion of opioid naïve patients ..."*

558. Purdue also promoted its drugs for "opioid-naïve" patients using the deceptive term "first line opioid." "First line" is a medical term for the preferred first step in treating a patient. Opioids are not an appropriate first line therapy. Nevertheless, Purdue's internal documents and testimony from sales representatives shows that Purdue repeatedly promoted OxyContin as "first line" — "the first thing they would take to treat pain."

559. A particularly insidious aspect of Purdue's focus on "naïve" patients, and on keeping patients on opioids longer, was its savings card program. The cards provided a discount on a patient's first five prescriptions. In 2012, Purdue's internal 10-year plan highlighted its discovery that opioid savings cards kept patients on opioids longer: "more patients remain on

OxyContin after 90 days." The savings card program was incredibly lucrative -- the return on investment for Purdue was 4.28, so that every $1,000,000 Purdue gave away in savings came back to Purdue as $4,280,000 in revenue because patients stayed on dangerous opioids longer. Discounts could have cut Purdue's revenue ***if*** patients took opioids for a short time. But Purdue's internal 10-year plan highlighted its discovery that opioid savings cards kept patients on opioids longer: "more patients remain on OxyContin after 90 days."

560. Purdue sales representatives, including the Purdue Sales Representatives Grace and Gatling, did not disclose to doctors that "opioid naïve" patients faced greater risks of overdose and death. Purdue focused on less sophisticated prescribers, such as its "core" prolific prescribers, and certain nurses and PAs who might be more vulnerable to persuasion by its sales representatives.

B. Increasing Dosages and Increasing Them Quickly to Keep Patients on Longer

561. In order to promote long-term sales, the Marketing Defendants promoted the prescription of higher dosages of opioids. There were several dimensions to this. First, the Marketing Defendants charged more for the higher dosages. More importantly, patients who took higher dosages would stay on opioids longer.

562. At Purdue, staff, from sales representatives to senior management including the Purdue Individual Defendants, regularly and candidly discussed internally the imperative of increasing prescribed dosages. Accordingly, Purdue's second most important sales tactic (after frequent sales representative visits, the most important strategy employed by Purdue) was to cause prescribers to prescribe higher doses. This was manifested in Purdue's *Individualize the Dose* campaign, and was communicated to prescribers in sales representatives' visits. Sales representatives were relentlessly pressured to increase the average doses prescribed by the prescribers in their territories. An aspect of this strategy was to encourage faster upward *titration*,

that is moving quickly from smaller to larger doses. The lowest dosage of Purdue's Butrans product, for example, was described to prescribers as an "introductory" dose that would presumptively be increased for most if not all patients.

563. Purdue secretly determined that pushing patients to higher doses would keep them on opioids longer. Purdue developed tactics specifically to keep patients hooked on opioids longer, which it called by the euphemism: "*Improving the Length of Therapy*" — sometimes abbreviated as "LOT" or "LoT." Purdue taught its employees that there is "a direct relationship" between getting patients on higher doses and keeping them on Purdue's opioids longer.

564. The Marketing Defendants' focus on increasing dosages, and increasing the duration of opioid usage, had devastating consequences for patients. Patients exposed to higher dosages, and for longer periods of time, are many times more likely to become addicted, and to overdose.

V. The Marketing Defendants' Scheme Succeeded, Creating a Public Health Epidemic

A. The Marketing Defendants' Dramatically Expanded Opioid Prescribing and Use

565. The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and they worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

566. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated $15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives

and targeting our marketing efforts to pain specialists."[251] Actiq became Cephalon's second best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million.[252] Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[253]

567. Each of the Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors' prescribing before and after detailing visits, and at various levels of detailing intensity, and before and after speaker programs. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants' opioids), and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids or to switch to "safer" opioids, such as ADF.

568. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior.[254] The effects of sales calls on prescribers'

---

[251] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.
[252] Carreyrou, *Narcotic Lollipop*.
[253] *Id.*

[254] *See, e.g.*, P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014

behavior is well documented in the literature. One study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

569. Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.[255] These results are directly due to the Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

570. Thus, both independent studies and Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

B. The Marketing Defendants' Deception in Expanding Their Market Created and Fueled the Opioid Epidemic.

571. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic

---

(2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); *see also* A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

[255] CS Hwang et al., *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175 JAMA Intern. Med. 302 (2014), doi: 10.1001/jamainternmed.2014.6520, https://www.ncbi.nlm.nih.gov/pubmed/25485657.

exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[256] It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

572. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[257]

573. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

VI. Each of the Marketing Defendants Made Materially Deceptive Statement and Concealed Material Facts

574. As alleged herein, the Marketing Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course of manufacturing, marketing, and selling prescription opioids. The Marketing Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

---

[256] Theodore J. Cicero et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16 Pharmacopidemiology and Drug Safety, 827-40 (2007), doi: 10.1002/pds.1452, https://www.cdhs.udel.edu/content-sub-site/Documents/Publications/Relationship%20Between%20Therapeutic%20Use%20and%20Abuse%20of%20Opioid%20Analgesics.pdf.

[257] *See* Califf,**Error! Bookmark not defined.** et al., *supra* n. 29.

575. As a part of their deceptive marketing scheme, the Marketing Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, the Marketing Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Marketing Defendants' misrepresentations.

A. Purdue

576. Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

577. More specifically, Purdue made and/or disseminated deceptive statements, and promoted a culture that mislead doctors and patients into believing opioids were safe for chronic care, including, but not limited to, the following:

a. In 1998, Purdue distributed 15,000 copies of an OxyContin video to physicians without submitting it to the FDA for review, an oversight later acknowledged by Purdue. In 2001, Purdue submitted to the FDA a second version of the video, which the FDA did not review until October 2002—after the General Accounting Office inquired about its content. After its review, the FDA concluded that the video minimized the risks from OxyContin and made unsubstantiated claims regarding its benefits to patients.[258]

b. According to training materials, Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that "fewer than one per cent" of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)[259]

c. Andrew Kolodny, the co-director of the Opioid Policy Research Collaborative, at Brandeis University, has worked with hundreds of patients addicted to opioids. He has stated that, though many fatal overdoses have resulted from opioids other than OxyContin, the crisis was initially precipitated by a shift in the culture of prescribing—a shift carefully engineered by Purdue. "If you look at the prescribing trends for all the different opioids, it's in 1996 that prescribing really takes off," Kolodny said. "It's not a coincidence. That was the year Purdue launched a multifaceted campaign that misinformed the medical community about the risks."[260]

d. "Purdue had a speakers' bureau, and it paid several thousand clinicians to attend medical conferences and deliver presentations about the merits

[258] Keefe, *Empire of Pain*, *supra* n. 97.
[259] *Id.*
[260] *Id.*

> of the drug. Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton. Such spending was worth the investment: doctors who attended these seminars in 1996 wrote OxyContin prescriptions more than twice as often as those who didn't. The company advertised in medical journals, sponsored Web sites about chronic pain, and distributed a dizzying variety of OxyContin swag: fishing hats, plush toys, luggage tags. Purdue also produced promotional videos featuring satisfied patients—like a construction worker who talked about how OxyContin had eased his chronic back pain, allowing him to return to work. The videos, which also included testimonials from pain specialists, were sent to tens of thousands of doctors. The marketing of OxyContin relied on an empirical circularity: the company convinced doctors of the drug's safety with literature that had been produced by doctors who were paid, or funded, by the company."[261]

e. Purdue encouraged sales representatives to increase sales of OxyContin through a lucrative bonus system, which resulted in a large number of visits to physicians with high rates of opioid prescriptions. In 2001, Purdue paid $40 million in bonuses to its sales representatives.[262]

f. Purdue claimed that the risk of addiction from OxyContin was extremely small and trained its sales representatives to carry the message that the risk of addiction was "less than one percent," while knowing that there was no empirical support for that statement.

g. By 2003, the Drug Enforcement Administration had found that Purdue's "aggressive methods" had "very much exacerbated OxyContin's widespread abuse." Rogelio Guevara, a senior official at the D.E.A., concluded that Purdue had "deliberately minimized" the risks associated with the drug.[263]

578. "From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue's national speaker bureau. It is well documented that this type of pharmaceutical company symposium influences physicians' prescribing even though the

---

[261] *Id.*
[262] Keef, *Empire of Pain*, *supra* n. 97.
[263] *Id.*

physicians who attend such symposia believe that such enticements do not alter their prescribing patterns."[264]

579. As noted above, Purdue utilized Front Groups to help disseminate and defend its false messages. Between January 2012 and March 2017, Purdue made the following contributions:

Academy of Integrative Pain Management	$1,091,024.86
American Academy of Pain Management	$725,584.95
ACS Cancer Action Network	$168,500.00[265]
American Chronic Pain Association	$312,470.00
American Geriatrics Society	$11,785.00[266]
American Pain Foundation	$25,000
American Pain Society	$542,259.52
American Society of Pain Educators	$30,000
American Society of Pain Management Nursing	$242,535.00
The Center for Practical Bioethics	$145,095.00

[264] Art Van Zee, MD, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. Journal of Public Health 2 (February 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

[265] Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017).

[266] The AGS reported that Purdue also provided $40,000 in "corporate roundtable dues" to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

U.S. Pain Foundation	$359,300.00
Washington Legal Foundation	$500,000.00
TOTAL	$4,153,554.33

580. The Purdue Individual Defendants reinforced Purdue's sales visits with dozens of other deceptive tactics aimed at Mississippi. The Purdue Individual Defendants wrote deceptive pamphlets and mailed them to doctors in Mississippi. The Purdue Individual Defendants used all these deceptive tactics to collect money in Mississippi, by getting more Mississippi patients on opioids, at higher doses, for longer periods of time.

581. Purdue streamed videos to Mississippi doctors on its OxyContin Physicians Television Network. Purdue hired the most prolific opioid prescribers in Mississippi as spokesmen to promote its drugs to other doctors.

582. Purdue promoted its opioids to Mississippi patients with marketing that was designed to obscure the risk of addiction and even the fact that Purdue was behind the campaign.

B. Endo

583. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

C. Janssen

584. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

D. Assertio

585. Defendant Assertio has, since at least October 2011, made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their

statements deceptive with respect to Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER, including, but not limited to:

a. Promoting the usage of Lazanda with patients not suffering from cancer;

b. Endorsing, supporting, and pressuring its sales representative to target pain management physicians, particularly those who historically wrote large numbers of Lazanda-like drugs;

c. Discouragement of sales representatives from targeting physicians treating cancer patients in contradiction to the FDA approved warning indicating that Lazanda is only indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain;"

d. Training of sales representatives on how to deal with pushback from physicians;

e. Promotion of Nucynta and Nucynta ER for all manner of pain management while downplaying the drug's addictive nature;

f. Promoting its drugs as a safer alternative than other opioids;

g. Telling investors that Depomed is safe. August Moretti, Assertio's Senior Vice President and Chief Financial Officer, stated that "[a]lthough not in the label, there's a very low abuse profile and side effect rate."

E. Cephalon

586. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing and speakers' bureau events.

F. Actavis

587. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

588. A Kadian prescriber guide deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. Kadian's prescriber guide is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.

G. Mallinckrodt

589. Defendant Mallinckrodt made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating and promoting publications that misrepresented and trivialized the risks of addiction;

b. Creating and promoting publications that overstated the benefits of opioids for chronic pain; and

c. Making deceptive statements about pseudoaddiction.

DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS

590. The Marketing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

591. Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Marketing Defendants' deceptive marketing caused prescribing not only of their opioids, but also of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

592. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has

quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[267] Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[268]

I. All Defendants Have a Duty to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders

593. Multiple sources impose duties on Defendants with respect to the supply of opioids, including the common law duty to exercise reasonable care.

594. Each Defendant was required to register with the State of Mississippi. Miss. Code Ann. § 41-29-125.

595. The Defendants also had legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids under Mississippi law.

596. Pursuant to Mississippi law, Defendants must adhere to Mississippi's controlled substances law in the sale of controlled substances. *See* Miss. Code Ann. § 41-29-125(b). (" Persons registered . . . to manufacture, distribute, dispense or conduct research with controlled substances may possess, manufacture, distribute, dispense or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this article.") All Defendants have a duty to report suspicious orders in order to prevent diversion.[269] Pharmacies are required to ensure that opioid prescriptions they fill are

---

[267] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., et al., "Increases in drug and opioid overdose deaths—United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.

[268] *Id.*

[269] Federal requirements impose a non-delegable duty upon registrants to design and operate a system to disclose to the registrant suspicious orders of controlled substances. "The registrant shall design and

written for a legitimate patient for a legitimate medical need. *See* Miss. Code Ann. § 41-29-137(f) ("[A] 'valid prescription' means a prescription that is issued for a legitimate medical purpose"). Pharmacies are also required to track prescriptions for controlled substances and report suspected abuse and misuse of controlled substances in compliance with federal law. Miss. Code Ann. § 73-21-127.

597. Further, "[p]ersons registered to manufacture, distribute or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the [State licensing boards] may issue." Miss. Code Ann. § 41-29-133.

598. Each Defendant's actions were in violation of Mississippi law, as set out above, and also including Miss. Code Ann. § 41-29-141, which forbids unlawful distribution of controlled substances; and § 41-29-139, which forbids the trafficking of controlled substances.

599. In addition to reporting all suspicious orders, the Distributor Defendants must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the recipient can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F. 3d 206 (D.C. 2017). Regardless, all flagged orders must be reported. *Id.*

600. These prescription drugs are regulated for the purpose of providing a "closed"

---

operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency" 21 C.F.R. § 1301.74(b).

system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[270]

601. "Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities."[271]

602. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction, with costs and damages necessarily inflicted on and incurred by Plaintiffs and others.

603. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality, along with the costs imposed upon Plaintiffs and others associated with the treatment of these conditions and related health consequences caused by opioid abuse.

604. Finding it impossible to legally achieve their ever-increasing sales ambitions, Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

---

[270] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[271] Brief for Healthcare Distribution Mgmt. Association and National Ass'n of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 (hereinafter Brief for HDMA and NACDS). The Healthcare Distribution Mgmt. Ass'n (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation and Cardinal Health, Inc. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last accessed Aug. 1, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/%20about/mission/ (last accessed Aug. 1, 2018).

605. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Marketing Defendants and customers, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

606. Distributor Defendants had financial incentives from the Marketing Defendants to distribute higher volumes and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

607. The Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The Washington Post has described the

practice as industry-wide, and the Healthcare Distribution Alliance ("HDA") includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to "downstream registrants", meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

608. A dramatic example of the use of prescription information provided by IMS Health was described in Congressional testimony:

> Mr. Greenwood: Well, why do you want that [IMS Health] information then?
>
> Mr. Friedman: Well, we use that information to understand what is happening in terms of the development of use of our product in any area.
>
> Mr. Greenwood. And so the use of it--and I assume that part of it--a large part of it you want is to see how successful your marketing techniques are so that you can expend money in a particular region or among a particular group of physicians--you look to see if your marketing practices are increased in sales. And, if not, you go back to the drawing board with your marketers and say, how come we spent "X" number of dollars, according to these physicians, and sales haven't responded. You do that kind of thing. Right?
>
> Mr. Friedman: Sure.[272]

A. <u>Defendants' Use of Trade and Other Organizations</u>

609. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA

[272] *Oxycontin: Its Use and Abuse*, *supra* n. 101.

1. Pain Care Forum

610. PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

611. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[273] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[274]

612. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF.[275] In 2012, membership and participating organizations included Endo, Purdue, Actavis and Cephalon. Each of the Marketing Defendants worked together through the PCF. But the Marketing Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[276] The Distributor Defendants participated directly in the PCF as well.

---

[273] Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (Sept. 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy- amid-drug-epidemic (emphasis added).
[274] *Id.*
[275] *PAIN CARE FORUM 2012 Meetings Schedule*, (last updated Dec. 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.
[276] *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc. and the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation.

2. Healthcare Distribution Alliance

613. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants, including Actavis, Endo, Purdue, Mallinckrodt and Cephalon, were members of the HDA.[277] Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Marketing Defendants by advocating for the many benefits of members, including "strengthening . . . alliances."[278]

614. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[279] The HDA and the Supply Chain Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Marketing and Supply Chain Defendants.

615. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other's businesses.[280] For example, the manufacturer membership application must be signed by a

---

Executive Committee, Healthcare Distribution Alliance (last accessed on Aug. 1, 2018), https://www.healthcaredistribution.org/about/executive-committee%20.

[277] *Manufacturer Membership*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/membership/manufacturer (last accessed Aug. 1, 2018).

[278] *Id.*

[279] *Id.*

[280] *Id.*

"senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

616. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Anda, Cardinal, and Henry Schein and their subsidiaries.

617. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

618. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[281] The conferences also gave the Marketing and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[282] The HDA and its conferences were significant opportunities

---

[281] *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers (last accessed Aug. 1, 2018, and no longer available).
[282] *Id.*

for the Marketing and Distributor Defendants to interact at a high-level of leadership. The Marketing Defendants embraced this opportunity by attending and sponsoring these events.[283]

619. After becoming members of the HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributor and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.

---

[283] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference (last accessed Aug. 1, 2018).

620. The Distributor Defendants and Marketing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[284] For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers..." The Marketing Defendants used this information to gather high-level data regarding overall distribution and to direct the Distributor Defendants on how to most effectively sell prescription opioids.

621. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

622. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

623. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the Fall of 2008, the HDA published the *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance

[284] *Webinars*, Healthcare Distribution Alliance, (last accessed on Sept. 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

624. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the law. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

625. The Defendants' scheme had a decision-making structure driven by the Marketing Defendants and corroborated by the Distributor Defendants. The Marketing Defendants worked together to control the government's responses to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

626. The Defendants worked together to control the flow of information and to influence governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

627. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA remained artificially high. In so doing, they ensured that suspicious orders were not reported to the DEA, and,

further, in so doing, they ensured that the DEA had no basis for either refusing to increase production quotas or decreasing production quotas due to diversion.

628. The Defendants also had reciprocal obligations to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with reporting obligations.

629. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

630. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

B. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

631. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled

substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.[285]

632. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

C. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers

633. The ARCOS database reveals and/or confirms the identity of each wrongful opioid distributor. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Supply Chain Defendants and Marketing Defendants has only recently been disclosed to the public.

634. Publicly available information confirms that the Supply Chain Defendants and Marketing Defendants funneled far more opioids into Mississippi and communities across the United States than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Marketing Defendants, would have alerted them to potentially suspicious orders of opioids.

635. This information includes the following facts:

a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

[285] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;

d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

e. Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

636. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

637. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber-and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors").

638. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the Defendants identify suspicious orders or customers who were likely to divert

prescription opioids.[286] The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy purchased opioids from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and others. These questionnaires put the recipients on notice of suspicious orders.

639. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.[287]

640. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[288]

641. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by Cardinal (ArcLight), provided the Defendants with charts

---

[286] U.S. Dep't of Justice Drug Enforcement Administration, *Suggested Questions a Distributor should ask prior to shipping controlled substances*, https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr. & Kathleen H. Dooley, Esq. *Pharmaceutical Product Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

[287] A Verispan representative testified that the Supply Chain Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).

[288] Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf, Figure 2 at p. 3 (last accessed Aug. 1, 2018).

analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.[289]

642. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.[290] Defendants were, therefore, collectively aware of the suspicious orders that flowed from their facilities.

643. Defendants refused to identify, investigate, and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[291] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders, all for failure to report suspicious orders.[292]

644. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

---

[289] *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, at *467-471 (Feb. 22, 2011).
[290] In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vender, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id*; *see also* Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).
[291] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.
[292] *Id.*

> Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

645. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.[293] In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[294]

646. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked

---

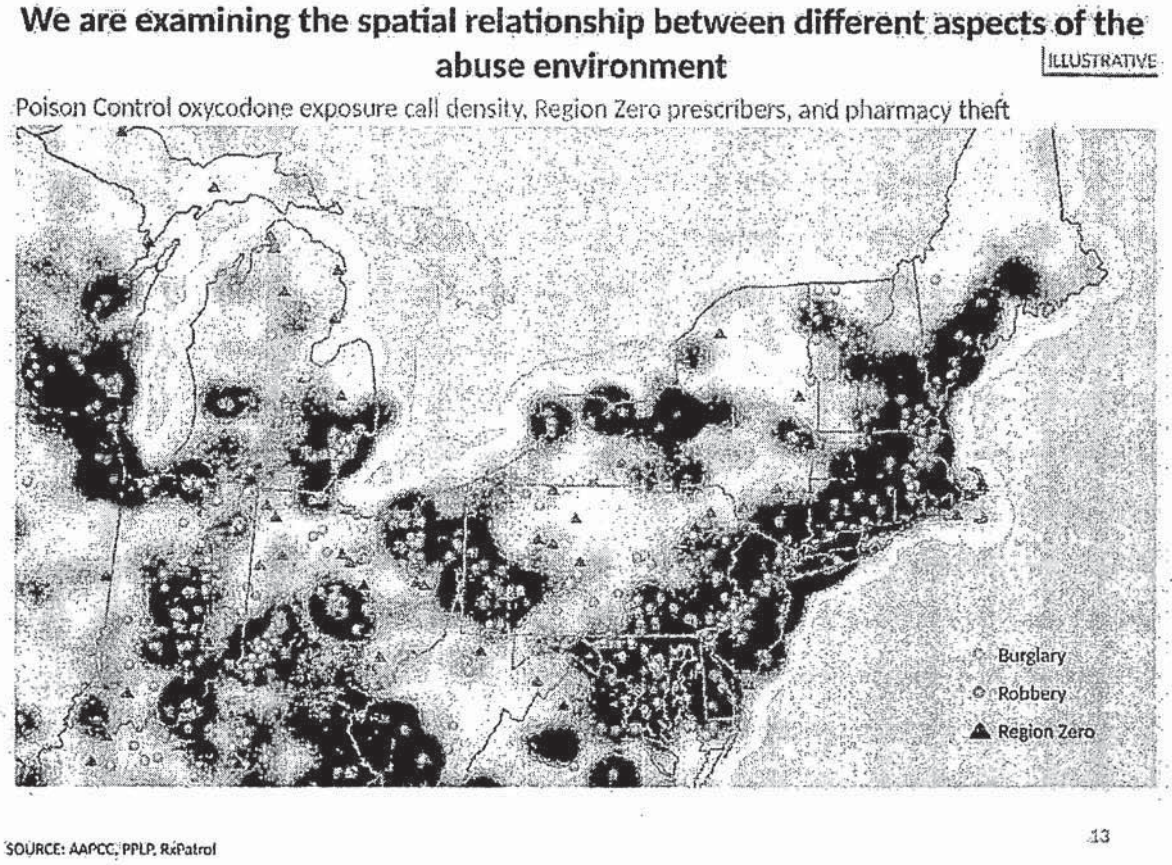
[293] *Pain Killer*, *supra* n. 94, at 298-300.
[294] *Id.*

like gang members," and that she felt "very certain that this an organized drug ring[.]"[295] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[296] This pill mill was not only distributing opioids locally - over a million pills were transported to the City of Everett, Washington, a city of around 100,000 people. Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle. The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

647. At Purdue, the Purdue Individual Defendants were well aware of the importance of prolific prescribers, which they and their staff referred to internally, at times, as "core," "super core," "high value" and "high potential" prescribers. In fact, it was an explicit, and significant, sales strategy to pay particular attention to actual and potential prolific prescribers, which the Purdue Individual Defendants understood to account for approximately 10% of overall revenues. At Purdue, the Sackler Co-Conspirators and Purdue Officer Co-Conspirators were aware that Purdue regularly received "Reports of Concern" about abuse and diversion of opioids, as well as reports of other adverse events, and also calls to Purdue's compliance "hotline." In July 2007, staff told the Sackler Co-Conspirators and Purdue Officer Co-Conspirators that more than 5,000 cases of adverse events had been reported to Purdue in just the first three months of 2007. Staff also told the Sackler Co-Conspirators and the Purdue Officer Co-Conspirators that Purdue

[295] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew*, LOS ANGELES TIMES (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.
[296] *Id.*

received 572 Reports of Concern about abuse and diversion of Purdue opioids during Q2 2007. Staff reported to the Sackler Co-Conspirators that they completed only 21 field inquiries in response. Staff also told the Sackler Co-Conspirators that they received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities. Purdue's self-interested failure to report abuses and diversion would continue, quarter after quarter, even though the 2007 Judgment required Purdue to report "potential abuse or diversion to the appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or even directing sales reps to stop visiting them, the Sackler Co-Conspirators chose to keep pushing opioids to whoever prescribed the most. Purdue also tracked prescribers from whom there was a substantial possibility of opioids having been diverted, or, at a minimum, grossly over-prescribed. It described these prescribers as, collectively, "Region Zero," and even generated a map, given to members of the Board, correlating these prescribers with poison control calls and pharmacy thefts.



Map presented to the Purdue Board in 2011

648. Once prescribers were categorized as part of "Region Zero," Purdue would eventually stop promoting to them, but it would *not* stop selling to them, and it would *not* report them to authorities. This would have been costly. Staff told John Stewart, the Sackler Co-Conspirators and the Board that the company was receiving a steadily rising volume of hotline calls and other compliance matters in this timeframe, reaching an all-time high during October, November and December 2010. Purdue made a calculated economic decision *not* to report suspicious prescribers and orders. Indeed, an internal Purdue study showed that the financial penalties imposed on drug companies for illegal marketing were "relatively small" when "compared to the perpetrating companies' profits." When the CDC issued a national warning

against the highest and most dangerous doses of opioids, Purdue studied prescription data to calculate how much profit it would lose if doctors followed the CDC's advice, and it elected not to.

649. Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers. However, this was done not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement.

650. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

651. This focus on marketing to the highest prescribers demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

652. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Marketing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon

this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[297]

653. But given the closeness with which they monitored prescribing patterns through IMS Health data, the Defendants either knew or chose not to know of the obvious drug diversions. In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

654. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company's policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

655. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Marketing Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

---

[297] *Pain Killer*, *supra* n. 94, at 179.

D. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

656. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities across America. Despite the notice described above, Defendants continued to pump massive quantities of opioids into communities in disregard of their legal duties to control the supply, prevent diversion, and report and take steps to halt suspicious orders.

657. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

658. For example, in 2017, the Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances - orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."

659. On December 23, 2016, Cardinal agreed to pay the United States $44 million to resolve allegations that it violated reporting requirements in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

a. "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";

b. "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and

c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

660. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection and antitrust laws, and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with Cardinal, shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities demonstrate that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million to the state; Cardinal settled for $20 million.

661. Henry Schein, too, is a repeat offender. Since the company's inception, it has been subjected to repeated disciplinary actions across the United States for its sale and/or distribution of dangerous drugs to persons or facilities not licensed or otherwise authorized to possess such drugs.

662. In 2014, Henry Schein Animal Health was investigated by the State of Ohio Board of Pharmacy due to its sale/distribution of wholesale dangerous drugs to an entity not holding a valid Ohio license. It reached a settlement with the Ohio Board of Pharmacy related to this investigation in 2015.

663. Records from a disciplinary proceeding against a Wisconsin-licensed medical practitioner reveal that from May 2005 through September 2006, Henry Schein continued to deliver opioids to the provider, despite the fact that his license had been suspended for inappropriate prescribing of opioids.

664. Thus, Defendants have admitted to disregarding their duties. They have admitted that they pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

E. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

665. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action - or may not know to take action at all.

666. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens.

667. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent

diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription-controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

668. Along the same lines, Defendant AmerisourceBergen has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

669. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Supply Chain Defendants, through their trade associations, HDMA and

NACDS, filed an amicus brief in *Masters Pharmaceuticals*, which made the following statements:[298]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

670. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Supply Chain Defendants not only acknowledged that they understood their obligations under the law, but they further asserted that their conduct was in compliance with those obligations.

671. Defendant Mallinckrodt similarly claims to be "committed . . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . ."

672. Other Marketing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its

[298] Brief for HDMA and NACDS, *supra* n. 271, 2016 WL 1321983, at *3-4, *25.

"constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement.[299]

673. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid epidemic.

674. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[300] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[301] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[302]

---

[299] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label* (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

[300] Purdue website, *Opioids With Abuse-Deterrent Properties*, \ http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last accessed Aug. 1, 2018).

[301] *Id.*

[302] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straighton-our-anti-diversion-

675. These public pronouncements create the false impression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

676. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

II. The Marketing Defendants' Unlawful Failure to Prevent Diversion and Monitor, Report, and Prevent Suspicious Orders

677. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Marketing Defendants under Mississippi law. Like the Distributor Defendants, the Marketing Defendants were required to register with the Mississippi Board of Pharmacy and the DEA to manufacture Schedule II controlled substances, like prescription opioids. *See* Miss. Code Ann. § 41-29-125.

678. Like the Supply Chain Defendants, the Marketing Defendants breached these duties. Mississippi state law requires that "[e]very person who manufactures, distributes or

---

programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

dispenses any controlled substance within this state" must comply with the requirements of Miss. Code Ann. 41-29-101, et seq. Miss. Code Ann. § 41-29-125.

679. Pursuant to Miss. Code Ann. § 41-29-133, "[p]ersons registered to manufacture, distribute or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the [State licensing boards] may issue."

680. The Marketing Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Marketing Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Marketing Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Marketing Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

681. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[303]

[303] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July

682. In the press release accompanying the settlement, the Department of Justice stated: "[Mallinckrodt] did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone." . . . "Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[304]

683. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[305]

684. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[306]

11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[304] *Id.*

[305] *Id.*

[306] Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download ("2017 Mallinckrodt MOA").

685. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

a. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to: conduct adequate due diligence of its customers;

b. Detect and report to the DEA orders of unusual size and frequency;

c. Detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

   i. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

   ii. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and

   iii. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

d. Use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

e. Take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information

> of diversion of Mallinckrodt product by those downstream customers.[307]

686. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 C.F.R. 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[308]

687. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[309]

688. The same duties imposed by law on Mallinckrodt were imposed upon all Marketing Defendants.

689. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized

---

[307] *Id.* at 2-3.
[308] *Id.* at 3-4.
[309] *Id.* at 5.

industry-wide among opioid manufacturers and distributors, including the other Marketing and Distributor Defendants.

690. Through, *inter alia*, the charge back data, the Marketing Defendants could monitor suspicious orders of opioids.

691. The Marketing Defendants failed to monitor, report, and halt suspicious orders of opioids as required by law.

692. The Marketing Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

693. The Marketing Defendants have misrepresented their compliance with the laws regulating controlled substances.

694. The wrongful actions and omissions of the Marketing Defendants that caused the diversion of opioids and which were a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' allegations of Defendants' unlawful acts below.

695. The Marketing Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States.

III. The Distributor Defendants' Unlawful Distribution of Opioids

696. The Distributor Defendants owe a duty under, *inter alia*, Mississippi common law and statutory law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

697. The foreseeable harm from a breach of these duties was the medical, social, and financial consequences rippling through society, arising from the abuse of diverted opioids for nonmedical purposes.

698. Each Distributor Defendant repeatedly and purposefully breached its duties under Mississippi law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes, with the resultant medical and financial damages.

699. For over a decade, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

700. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality, with social and financial costs borne by, among others, individuals, families and hospitals.

701. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

702. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a

wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

703. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported.

704. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

705. Because distributors are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on them to maintain effective controls to prevent diversion of controlled substances.

706. As the DEA advised the Distributor Defendants in a letter dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the

closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[310]

707. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[311]

708. The DEA's September 27, 2006 letter also warned the Distributor Defendants that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[312] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[313] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

709. The DEA sent a second letter to each of the Distributor Defendants on

---

[310] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) (hereinafter "Rannazzisi Letter)") ("This letter is being sent to every commercial entity in the United States registered with the Drug Enf't Admin. (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, ECF No. 14-51 (D.D.C. Feb. 10, 2012) (hereinafter "Letter from Joseph T. Rannazzisi to Cardinal Health").

[311] *See* Brief for HDMA and NACDS, *supra* n. 271, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

[312] Rannazzisi Letter, *supra* note 310, at 2.

[313] *Id.* at 1.

December 27, 2007.[314] This letter reminds the Distributor Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[315] The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive.
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[316]

710. Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[317]

711. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[318]

---

[314] *Id.* at 2.
[315] *See* Letter from Joseph T. Rannazzisi to Cardinal Health, *supra* n. 310.
[316] *Id.*
[317] *Id.*
[318] *See* Amicus Curiae Brief of Healthcare Distribution Mgmt. Ass'n in Support of App. Cardinal Health, Inc., *Cardinal Health, Inc. v. U.S. Dep't of Justice*, No. 12- 5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 (hereinafter "Brief of HDMA in Support of Cardinal").

712. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association (now known as the HDA, a front group of the Defendants, discussed below), the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[319]

713. The Federal Trade Commission ("FTC") has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with

[319] Healthcare Distribution Mgmt. Ass'n (HDMA)), Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, *filed in Cardinal Health, Inc. v. Holder*, Doc. No. 1362415 (App'x B), No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

714. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

715. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which the Distributor Defendants knew prescription opioids were likely to be diverted.

716. Each Distributor Defendant owes a duty to monitor, detect and refuse suspicious orders of prescription opioids, to report suspicious orders of prescription opioids and to prevent the diversion of prescription opioids into illicit markets.

717. The laws at issue here concerning the sale and distribution of controlled substances are also the public safety statutes and regulations of states in which Plaintiffs' hospitals operate.

718. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by state law which are required to legally acquire and maintain a license to distribute prescription opiates.

719. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

A. Inadequate Compliance Staffing and Training

720. First, the Distributor Defendants routinely failed to staff their compliance functions with qualified personnel, and failed to provide those compliance employees and their sales representatives with appropriate training. Even front-line compliance functions, such as approving threshold increases, detecting, blocking, and reporting suspicious orders, and terminating and/or suspending customers, were often assigned to operations, sales and administrative employees who had no experience with regulatory compliance of any kind.

B. Inadequate Scrutiny of Customers

721. None of the Distributor Defendants had a consistent practice of conducting appropriate due diligence of either prospective new customers or their existing customers. New customers were routinely on-boarded despite the acknowledged presence of unresolved red flags, and none of the Distributor Defendants ensured that additional investigations were conducted

when existing customers made suspicious orders, even when compliance staff flagged those orders as suspicious, blocked them, and reported them to the State.

722. Indeed, the Distributor Defendants routinely allowed their customers to make multiple suspicious orders within the same month, week, or even year, without conducting any additional due diligence of those customers. In fact, salespeople would warn customers when they were approaching their monthly threshold limits for ordering certain categories of controlled substances, putting them in a position to assist their customers in *evading* compliance reviews that would have otherwise occurred by manipulating the timing and volume of their orders.

723. Even where customers had to be blocked from ordering opioids in excess of their monthly threshold allowance multiple times within that month, the Distributor Defendants would allow those customers to resume ordering opioids the next month, at the same volume levels as before, without requiring any follow up investigation.

724. And none of the Distributor Defendants conducted periodic, unexpected due diligence audits of their customers, even among the easily identifiable and relatively small groups of pharmacies that consistently ordered the highest volumes of opioids. Instead, these pharmacies could go for years without the Distributor Defendants updating their knowledge of those customers' prescriber base, customer traffic patterns, and other relevant store conditions. Even when those pharmacies were scrutinized, the customer was often warned in advance.

C. Failure to Detect, Block and Report Suspicious Orders

725. The Distributor Defendants failed to report "suspicious orders," which the Distributor Defendants knew were likely to be diverted, to the relevant governmental authorities.

726. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

727. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

728. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

729. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities, including the DEA, of suspicious orders when discovered in violation of their duties under state law.

730. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific, and industrial channels.[320]

731. While the Distributor Defendants' policies nominally allowed for compliance staff to identify any order as suspicious, as a matter of practice, only orders that exceeded a customer's monthly threshold limit for a particular category of controlled substances would actually trigger a compliance review. As a result, untold numbers of opioid orders that should have been reviewed due to their unusual size or frequency, or their departure from the customers' normal ordering patterns, were never even checked to determine whether they were suspicious. Because the Distributor Defendants routinely allowed their customers to obtain information about the monthly threshold limits governing their orders of opioid products, orders customers made within the limits after being enabled to "game" them were improperly excluded from

[320] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

compliance review, when they all should have been checked to see whether the customers were deliberately structuring their orders to evade scrutiny.

732. Even as to orders that exceeded customers' monthly thresholds, the Distributor Defendants, over varying time periods, routinely failed to accurately identify those orders as suspicious. Instead, they released those orders for delivery based on perfunctory and unverified information provided by the customer, or for no documented reason at all. Moreover, even when the Distributor Defendants did identify orders as suspicious and did block them from delivery to customers, they routinely failed to report those suspicious orders to the State, sometimes going months or years without reporting any at all. When they did make suspicious-order reports, the reports were routinely incomplete, for example, by failing to identify all of the relevant suspicious orders for a customer, even when they were made within the same month, week, or even day.

733. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[321]

D. Distributor Defendants Failed to Suspend Suspicious Customers

734. The Distributor Defendants failed to act to suspend customers from ordering controlled substances, let alone terminate their accounts, even after compliance staff had blocked and reported dozens, or even hundreds, of suspicious orders from those customers. In the relatively rare instances where a customer had been terminated or suspended, the Distributor

[321] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy*, Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

Defendants allowed them to reinstate their accounts, or open accounts under new business names, without investigating and resolving the issues that had led to the initial termination or suspension.

E. Distributor Defendants Failed to Adequately Maintain Accessible Data Concerning Customers and Prescribers

735. None of the Distributor Defendants systematically stored, organized, and made accessible for reference information about their customers or their owners, pharmacists, and top prescribers, in order to allow for meaningful future compliance efforts.

736. The Distributor Defendants did not require compliance staff to obtain customers' prescriber information, and some actually changed their policies to *forbid* such inquiries, willfully blinding themselves to one of the most important indicators of diversion. While compliance staff and/or third-party investigators retained by the Distributor Defendants would sometimes flag prescribers as suspicious in the course of conducting due diligence of a pharmacy, that information was not stored or shared in any useable format. As a result, when the same suspicious prescriber appeared among another pharmacy's top prescribers, the compliance staff handling that subsequent due diligence investigation would have no way of knowing about this risk that had already been identified, unless they had personally handled the earlier investigation, and happened to remember the prescriber's name. Similarly, they made no effort to collect and compare information about pharmacies that made high-volume orders of opioids, had been flagged for making suspicious orders, or had been suspended or terminated for suspicious or illegal practices. As a result, compliance staff had no way of knowing that a pharmacy they were investigating shared ordering patterns or top prescribers with another risky, suspicious, and/or previously disciplined customer.

F. The Distributor Defendants Failed to Report Violations to Government Authorities

737. The Distributor Defendants failed to promptly report compliance violations to the State of Mississippi, and other governments. Indeed, even when they actually detected failures in their compliance systems, they made no effort to report those known incidents. More broadly, due to the combination of systematic failures riddling their compliance systems described above, none of the Distributor Defendants had the competence to effectively detect their own violations.

738. For example, if any of the relevant Distributor Defendants had conducted periodic audits of their own records of customers' orders, those customers' patterns of ordering in excess of their monthly threshold allowance for opioid products, the number of times those orders were released without justification, and the number of times those orders were blocked as suspicious without being reported to government agencies and/or triggering additional investigations, suspensions, or terminations, they would have each been obliged to report hundreds, if not thousands, of violations at a time.

739. In short, the Distributor Defendants deliberately lied to Mississippi and other states, both expressly and by omission, year in and year out, about the effectiveness of their compliance systems and the incidence of violations, so that they could fraudulently maintain their licenses to continue doing business in Mississippi and elsewhere.

740. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

G. Each of the Distributor Defendants Engaged in Wrongful Conduct

1. Cardinal

a. Cardinal's Flawed Written Policies Enabled Opioid Diversion

741. Cardinal's written policies for compliance were and are contained in Standard Operating Procedures ("SOPs") that apply to its various operating and sales departments. These SOPs were first implemented in 2008 and have since undergone several revisions.

742. These policies were fundamentally flawed in that they were not coordinated within the context of a consistent, unified umbrella policy to prevent the diversion of controlled substances, resulting in employees governed by one of the SOPs being unaware of the obligations imposed by other SOPs on other employees, even when effective anti-diversion measures required that understanding and coordination. Furthermore, these documents are not readily available even to the employees charged with implementing them.

743. In addition, Cardinal's SOPs and policies contained numerous gaps that would have prevented them from effectively preventing diversion, even if enforced. For example, these policies:

a) Allowed compliance staff to approve on boarding new accounts with no formal mechanism to ensure review and approval by a supervisor;

b) Allowed onboarding of new accounts even where customers failed to provide requested information about other suppliers, dispensing data, and top prescriber information; and

c) Allowed compliance staff to release a customer's first order in excess of its monthly threshold, regardless of whether the customer made other orders in excess of the same drug threshold at the same time.

b. Cardinal's Failure to Effectively Prevent Diversion in Practice

744. At all relevant times, Cardinal failed to employ qualified compliance staff to implement these policies, failed to adequately train those compliance staff or its sales

representatives concerning Cardinal's anti-diversion duties, and failed to enforce even the defective policies it had in place.

745. Cardinal failed to install qualified personnel in key compliance positions. For example, Cardinal's front-line "New Account Specialists" and "Analysts," responsible for onboarding new customers and monitoring existing customers, respectively, were routinely recruited from the ranks of the company's existing pool of administrative assistants. These employees, who had no experience in regulatory compliance, were generally supervised by pharmacists or other professionals with no prior experience in supervising investigative functions.

746. Moreover, Cardinal failed to provide meaningful training to either these unqualified compliance personnel or sales representatives. Instead, Cardinal expected the compliance staff to "learn on the job" through informal in-person "team meetings." Due to the lack of proper training and clear guidelines, compliance staff did not fully understand critical components of their jobs and often developed their own procedures and benchmarks for reviewing customers.

747. Unsurprisingly, these unqualified and untrained staff routinely failed to follow even the most basic procedures required under the company's various SOPs. In addition, Cardinal allowed customers to reinstate their accounts through the new account onboarding process despite having compliance red flags.

748. Even to staff charged with investigations and anti-diversion, the message was clear: without sales, there is no Cardinal. Indeed, many of Cardinal's policies and practices have prioritized sales over regulatory obligations.

749. In 2012 and 2013, Cardinal took significant steps to renew focus on increased sales at the cost of a robust and responsible compliance structure, thereby keeping as customers pharmacies that it knew or should have known were high risk for diversion of opioids. For example, Cardinal:

a) Continuously reduced the due diligence information collected from prospective and existing customers, diluting the customer questionnaire, removing the requirements to collect photos of the pharmacies, and ceasing to ask about top prescribers;

b) Expanded the geographic scope of investigators with essential regional knowledge of, for example, top prescribers and their locations relative to the pharmacies where their prescriptions were being filled, thus reducing the investigators' efficacy;

c) Restricted the information reviewed from site visits by first removing the investigator comment section and for a time eliminating written reports entirely; and

d) Demoted, moved to non-compliance functions, or let go several staff members who articulated an interest in expanding the company's compliance functions, aggressively scrutinizing pharmacy customers, and/or terminating problematic customers.

750. As to existing customers, Cardinal routinely failed to follow the SOP's procedures for detecting, monitoring, and reporting suspicious orders. Cardinal's compliance staff routinely released orders in excess of a customer's threshold without conducting the follow-up investigation and providing the detailed written justification called for by the SOPs.

751. Even where Cardinal did block customers' orders and report them as, it routinely took no steps to suspend or terminate those customers pending further investigation, and instead allowed them to continue receiving their threshold amount of opioids month after month thereafter, regardless of whether the customer continued to make additional suspicious orders.

752. Between 2012 and 2017, for example, Cardinal reported twelve or more opioid related suspicious orders for at least one year-the equivalent of one per month-for hundreds of

pharmacies nationwide. Those pharmacies had several known red flags m their shipment orders and prescription data. More than half of these pharmacies: (a) exceeded the 90th percentile in the State in terms of opioid volume shipped; (b) exceeded the 90th percentile in the State in terms of oxycodone volume shipped; and (c) exceeded the 90th percentile in the State in terms of median strength of opioids prescribed per day. Nonetheless, even after reporting twelve or more opioid-related suspicious orders for one of these pharmacies, Cardinal continued to ship opioids, on average, for *more than three years.* Within this group of suspect pharmacies that Cardinal did nothing to control, these included particularly egregious cases in which Cardinal reported more than 50 opioid-related suspicious orders per year-the equivalent of *one suspicious order per week* to the authorities for *three or more* consecutive *years.*

753. In still other instances, neither Cardinal nor other distributors reported numerous suspicious orders, but almost certainly should have, given that a handful of prescribers were responsible for writing an unusually high percentage of the pharmacy's opioid prescriptions. By itself, having a high concentration of opioid prescriptions written by a small number of providers is a known red flag for opioid diversion. Subsequently, these pharmacies had among the highest percentage of prescriptions written by providers who were indicted or convicted on opioid-related prescribing and distribution charges.

754. Examples of egregious cases identified in a complaint recently filed by an attorney general included:

a) A pharmacy in the 99th percentile in the state, to which Cardinal reported an average of 85 suspicious orders per year for five years, the equivalent of more than once a week, yet as of 2018, as of 2018, this pharmacy continued to receive opioids from Cardinal.

b) A pharmacy in the 95th percentile in the state, to which Cardinal, from 2012 to 2018, shipped more than 20,000 grams of opioids, the equivalent of about thirteen 30mg oxycodone pills for every person in the county.

c) A pharmacy in the 90th percentile where more than 20% of its customers have received opioid prescriptions by three or more doctors in a six-year period, and to which Cardinal continued to ship opioids after other distributors had issued 223 SORs.

d) A pharmacy in the 99th percentile where approximately 60% of prescriptions were written by prescribers who were later indicted or convicted, and to which Cardinal has failed to issue a single SOR as of December 2017.

755. Finally, even if Cardinal had conducted due diligence to investigate its high-volume opioids customers, Cardinal's failure to implement any system to store and share information about their suspicious customers and/or suspicious prescribers would have compromised the effectiveness of any such investigation.

756. Due to these flaws, Cardinal routinely continued to supply pharmacies that filled prescriptions for prescribers that had been flagged in its own (infrequent) investigations of other pharmacies as likely sources of diversion.

c. Cardinal Was Put on Notice of its Wrongful Conduct

757. In addition to numerous instances, including examples cited above, in which Cardinal's own employees acknowledged failures in its compliance systems, the company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties.

758. To date, Cardinal has paid a total of $98 million in fines and other amounts involving multiple DEA and various state actions relating to its improper management and distribution of opioids to pharmacies across the United States.

759. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses[322] around the United States (the "2008 Cardinal Settlement Agreement").[323] These allegations included failing to report to the DEA thousands of suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.[324]

760. In connection with the 2008 Cardinal Settlement Agreement, the DEA stated that "[d]espite [its] repeated attempts to educate Cardinal on diversion awareness and prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for controlled substances filled by its distribution facilities located throughout the United States."[325] The DEA concluded that "Cardinal's conduct allowed the 'diversion' of millions of dosage units of hydrocodone from legitimate to non-legitimate channels."[326]

761. As part of the 2008 Cardinal Settlement Agreement, Cardinal agreed to "maintain a compliance program designed to detect and prevent diversion of controlled substances as

---

[322] Including its Lakeland, Florida facility. https://www.dea.gov/pubs/pressrel/pr100608.html. In 2012, Cardinal described the Lakeland facility as shipping "an average of about 4 million dosage units of prescription drugs, including about 500,000 dosage units of controlled substances, on a monthly basis to more than 5,200 customers in Florida, Georgia and South Carolina. The volume of prescription drugs distributed makes the Lakeland facility the largest prescription drug wholesaler in Florida." *Cardinal Health, Inc. v. Eric Holder, Jr., Att'y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-1, at 6; 3-13 at 2; 3-15 (Feb. 3, 2012).

[323] Settlement and Release Agreement and Administrative Memorandum of Agreement (Sept. 30, 2008), a cached version is *available at* https://webcache.googleusercontent.com/search?q=cache:O7Te0HbVfpIJ:https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf+&cd=2&hl=en&ct=clnk&gl=us; Press Release, U.S. Att'y Office, Dist. of Colo., Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

[324] *Id.*

[325] U.S. Att'y Office, Dist. of Colo., *Cardinal Health Inc. Agrees to Pay $34 Million to Settle Claims that It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

[326] *Id.*

required by the CSA and applicable DEA regulations."[327] However, in 2012, the DEA issued an "immediate suspension order," suspending Cardinal's registration with respect to Cardinal's drug distribution facility in Lakeland, Florida. That order stated "Despite the [2008 Cardinal Settlement Agreement], the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA]."[328] For example, from "2008-2009, Cardinal's sales to its top four retail pharmacies [in the State of Florida] increased approximately 803%. From 2009 to 2010, Cardinal's sales to its top four retail pharmacies [in the State of Florida] increased 162%."[329]

762. In 2012, Cardinal reached another settlement with the DEA relating to its failure to "conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels" resulting in systemic opioid diversion in its Florida distribution center (the "2012 Cardinal Settlement Agreement").[330] Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area pharmacies, nearly fifty times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years.[331] The DEA found that Cardinal's own investigator warned Cardinal against selling opioids to these pharmacies, but that Cardinal did nothing to

---

[327] *Cardinal Health, Inc. v. Eric Holder, Jr., Att'y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-4, at ¶ 2 (Feb. 3, 2012).
[328] *Id.* at ¶ 3.
[329] *Id.* at ¶ 4.
[330] Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed August 1, 2018); Press Release, Drug Enf't Admin., DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), https://www.dea.gov/pubs/pressrel/pr051512.html.
[331] *Id.*

notify the DEA or cut off the supply of drugs to the suspect pharmacies.[332] Instead, Cardinal's opioid shipments to the pharmacies increased.[333]

763. In the 2012 Cardinal Settlement Agreement, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances as required by the CSA, on or before May 14, 2012; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.[334]

764. In December 2016, Cardinal again settled charges that it had violated the CSA by failing to prevent diversion of oxycodone for illegal purposes, this time for $44 million (the "2016 Cardinal Settlement Agreement").[335] The settlement covered DEA allegations that Cardinal had failed to report suspicious orders across Washington, Maryland, New York, and Florida.[336] The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case.[337] The settlement also covered a Cardinal subsidiary, Kinray, LLC, which failed to report a single suspicious order despite shipping oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate.[338]

---

[332] *Id.*
[333] *Id.*
[334] Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed August 1, 2018).
[335] U.S. Att'y Office, Dist. of Md., *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016) https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.
[336] *Id.*
[337] *Id.*
[338] *Id.*

d. Cardinal Actively Marketed Prescription Opioids

765. Cardinal worked to increase sales of opioids through a range of in-house marketing platforms directed at prescribers, pharmacists, and consumers, implemented nationally.

766. Cardinal not only offers marketing services to its drug manufacturer clients, it incentivizes and encourages manufacturers to use these marketing channels as a way of building their business and increasing sales of prescription opioids.

767. Cardinal utilized a variety of marketing programs to promote sales of prescription opioids, including direct consumer marketing, direct mail marketing, email marketing, marketing in customer newsletters, telemarketing, advertisement on ordering platform, pharmacy rebates, and auto-shipments.

768. Purdue and other manufacturers worked hand-in-glove with Cardinal to promote their products through the distributors to pharmacies and pharmacists.

769. Cardinal profited in two ways from its marketing activities: (1) it was paid by the drug manufacturers to promote their prescription opioids, and/or (2) it was paid from increases in pharmacy drug sales that resulted from these marketing efforts.

770. The targeting of pharmacists by Cardinal in its marketing activities was particularly problematic because of Cardinal's existing and often long-term business relationships with pharmacies—with whom Cardinal shared a legal responsibility to prevent diversion. Opioid distributors, like Cardinal, were in a unique and trusted position in the controlled substances supply chain from which they could have spoken truthfully to their pharmacy customers about the serious risks posed by opioids (including the risk of diversion). They could have remained silent about the benefits and risks of opioids, and simply filled orders

and shipped drugs. Instead, Cardinal abused its unique position for profit, by contributing to the chorus of deception surrounding opioids.

771. To engage in the promotion of controlled substances at all, under the circumstances detailed in this Complaint, was a dereliction of Cardinal's duties to prevent opioid diversion. Through these marketing activities, Cardinal contributed to and reinforced the deceptive and misleading marketing messages that healthcare providers received about opioids through other channels. Moreover, much of the Cardinal's marketing content was deceptive, because it either affirmatively misrepresented the benefits and risks of prescription opioids, or it omitted important information about the risks of prescription opioids. Cardinal knew or should have known that these marketing messages—particularly those that misrepresented or omitted material information about the potential for diversion or risks of addiction associated with prescription opioids—were deceptive.

772. Through marketing activities, Cardinal built upon, reinforced, and profited from the drug manufacturers' campaign to deceive healthcare providers about the risks and benefits of prescription opioid use—a campaign that encouraged and normalized over-prescribing and over-dispensing of prescription opioids.

773. Cardinal made false statements that it had no role in influencing the prescribing or dispensing of prescription opioids and did not promote and market any pharmaceuticals-including opioids-directly to consumers.

2. AmerisourceBergen

a. AmerisourceBergen's Flawed Written Policies Enabled Opioid Diversion

774. AmerisourceBergen is the nation's third largest drug distributor in the country. AmerisourceBergen's written policies for compliance were and are contained within its

Diversion Control Program and its Order Monitoring Program ("COMP"). The programs are administered by AmerisourceBergen's Corporate Security and Regulatory Affairs ("'CSRA"). From 2007 to 2015, the program's specifics were scattered through a series of policy and procedure documents, and which were not uniform for AmerisourceBergen and its subsidiary, Bellco Health, which it acquired in 2007. AmerisourceBergen compliance policies are flawed from the point of initial new customer on boarding. Since 2007, AmerisourceBergen has generally required a customer questionnaire, a site visit, license verification, and online investigation as part of its new customer due diligence process. A central component of AmerisourceBergen's new customer procedure is its Retail Pharmacy Questionnaire ("590 Form"). The form asks for information about other distributors, disciplinary history, customer payment methods, percentages of controlled substances, usage numbers for specific high-risk drugs, and top prescribers of opioids, among other questions. Though the form requests information about prescribing physicians, it is not AmerisourceBergen's policy to perform news searches on those prescribers as part of the new customer procedure, and controlled substances could account for up to-of prescriptions dispensed before triggering additional investigation.

775. AmerisourceBergen does not require new customers to provide usage reports or dispensing data as part of the on boarding process. By relying on these customers to self-report without any documented verification, AmerisourceBergen does not fulfill its obligation of truly knowing its customers' business practices.

776. Both prior to and after program revision, AmerisourceBergen's policies have allowed for frequent threshold manipulation to avoid orders being held for review, rejected from shipment, or reported as suspicious. Staff reviewing the form have high benchmarks for these numbers before considering them red flags.

777. AmerisourceBergen's policies are not sufficient to comply with the requirements of T.C.A. § 53-1-101 and similar requirements of other states. Under AmerisourceBergen's deficient policies, it does not hold for review orders that only meet one of these qualifications. By limiting the orders even held for review, AmerisourceBergen's policy does not fulfill its obligation to identify even orders of interest, much less suspicious orders.

778. Examples of egregious cases identified recently in a complaint filed by a state attorney general included:

a) A pharmacy at or above both the 99th percentile in terms of both number of opioid orders and total opioid weight, at which, between 2014 and 2016, more than 10% of its prescriptions were written by prescribers who were later indicted or convicted of opioid-related prescribing and distribution charges, concerning which AmerisourceBergen reported nearly 200 SORs in 2013-14, and to which as of 2018, AmerisourceBergen was still serving as this pharmacy's primary opioid distributor;

b) A pharmacy where, between 2013 and 2017, 77% of its prescriptions, on average, were written by prescribers who were later indicted or convicted, including 90% in 2014, and to which Amerisource appears to have only stopped shipping in 2017; and

c) A pharmacy that exceeded the 95th percentile for the percentage of oxycodone volume shipped for five years straight (2012 to 2016), where on average 58% of its opioid prescriptions were paid in cash (99th percentile), where for three consecutive years (2013 to 2015) approximately half of all opioid scripts were filled by prescribers who were later convicted, and which, as of 2018, was still a customer of AmerisourceBergen.

b. AmerisourceBergen's Failure to Effectively Prevent Diversion in Practice

779. At all relevant times, AmerisourceBergen failed to employ sufficient numbers of qualified compliance staff to implement these policies, failed to ensure those compliance staff were meeting AmerisourceBergen's anti-diversion duties, and failed to enforce even the

defective policies it had in place. Among other deficiencies, AmerisourceBergen failed to sufficiently staff its compliance departments.

780. Since the integration of Bellco into AmerisourceBergen and the revamp of its Diversion Control Program in 2015, the company has increased anti-diversion staffing, but has not significantly increased the number of fully trained ground level employees. Since that time, AmerisourceBergen has maintained only five to seven front-line employees on its Diversion Control Team, responsible for reviewing new customers and monitoring its existing customers.

781. Many of AmerisourceBergen's compliance violations begin with its new customer policy. The process relies heavily on the customer 590 Form, given that AmerisourceBergen only requests dispensing information from new customers when it already knows of potential issues. For example, dispensing data was requested recently in considering customers moving from distributor Morris & Dickson Company-including customers that prompted a DEA investigation because of their high-volume opioid purchasing.

782. Despite the 590 Form being so critical to understanding its customers and ensuring it can fulfill its regulatory obligations, and despite numerous other AmerisourceBergen procedures relying on reviewing or updating this form, AmerisourceBergen has had significant issues related to failing to perform even this baseline screening. Bellco Generics customers, for example, regularly completed the 590 Form independently, submitted it to Bellco, and were on boarded thereafter without receiving a site visit.

783. Disjunction between AmerisourceBergen and Bellco has led to many compliance failures. Until system integration in or around November 2015, staff had no systematic way of identifying dual customers. The lack of an integrated system also meant that thresholds were not coordinated between AmerisourceBergen and Bellco at any point. As a result, a dual customer

could have high thresholds set with both, could be exceeding both thresholds, or even having its threshold periodically increased with both, without detection. In or around April 2013, AmerisourceBergen implemented a policy for dual customers that prevented both AmerisourceBergen and Bellco from supplying controlled substances to the same customer, but implementation was spotty, and, in practice, only a small percentage of orders flagged for review are cancelled, and even fewer are deemed suspicious.

784. AmerisourceBergen has a high tolerance for compliance issues before it will terminate a customer. It still lacks an internal rule or policy that requires investigation of a customer based on a specific number of suspicious order reports. Even when customers were restricted, blocked, or terminated, AmerisourceBergen's system failed to ensure their accounts were de-activated.

785. The one area in which AmerisourceBergen has consistently stood out as compared to its major competitors is its unwillingness to identify suspicious orders, even among customers that regularly exceeded their thresholds and presented multiple red flags of diversion. During this time, numerous AmerisourceBergen opioid customers exhibited several common indicators of suspicious activity for multiple years. These flags included:

a) Scoring above the 90th percentile in the county for opioid order volume;

b) Scoring above the 90th percentile in the county for total opioid orders;

c) Scoring above the 90th percentile in the county for oxycodone order volume;

d) Scoring above the 90th percentile in the county for total oxycodone orders;

e) Scoring above the 90th percentile in the state for the percentage of oxycodone volume shipped out of all controlled substances shipped;

f) Filling prescriptions by prescribers who were later indicted or convicted on opioid-related prescribing and distribution charges;

g) Scoring above the 90th percentile in terms of percentage of patient doctor-shoppers;

h) Scoring above the 90th percentile in terms of percentage of cash payments; and

i) Scoring above the 90th percentile in terms of the median MME prescribed per day.

c. AmerisourceBergen Was Put on Notice of its Wrongful Conduct

786. AmerisourceBergen's deficiencies and failures did not go undetected. The company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties.

787. AmerisourceBergen has paid $16 million in settlements and had certain licenses revoked as a result of allegations related to the diversion of prescription opioids.

788. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.[339] Over the course of one year, AmerisourceBergen had distributed 3.8 million dosage units of hydrocodone to "rogue pharmacies."[340] The DEA suspended AmerisourceBergen's registration after determining that "the continued registration of this company constitutes an imminent danger to public health and safety."[341]

789. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.[342]

---

[339] Press Release, Drug Enf't Admin., *DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances* (Apr. 24, 2007), https://www.dea.gov/divisions/mia/2007/mia042407p.html.
[340] *Id.*
[341] *Id.*
[342] Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion,* Law360.com (Aug. 9, 2012), *available at* https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion.

H. The Distributor Defendants Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties

790. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under Mississippi law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

791. Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017), the Healthcare Distribution Management Association, n/k/a HDA, a trade association run by the Distributor Defendants, and the National Association of Chain Drug Stores ("NACDS"), an association of the National Retail Pharmacies (and similar persons), submitted amicus briefs regarding the legal duty of wholesale distributors. Denying inaccurately the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[343]

b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[344]

c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[345]

[343] Brief for HDMA and NACDS, *supra* n. 271, 2016 WL 1321983, at *4–5.
[344] *Id.* at *8 (citations and quotation marks omitted).
[345] *Id.* at *14.

d. The Associations complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[346]

e. The Associations alleged (inaccurately) that "DEA's regulations [ ] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[347]

f. Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[348]

792. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[349]

793. The Court of Appeals for the District of Columbia Circuit recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. In *Masters* Pharmaceuticals, the Court upheld the revocation of Masters Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. A distributor's investigation must dispel all

[346] *Id.* at *22.
[347] *Id.* at *24–25
[348] *Id.* at 26.
[349] *See* Brief of HDMA in Support of Cardinal, *supra* n. 318, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties.

794. Because of the Distributor Defendants' refusals to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[350] As noted above, the Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[351] These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

---

[350] Evaluation and Inspections Div., Off. of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* (May 2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[351] *Id.*

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On September 30, 2008, Cardinal entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

g. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone; and

h. On December 23, 2016, Cardinal agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

795. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's

license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[352]

796. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

797. For example, a Cardinal executive claimed that it uses "advanced analytics" to monitor its supply chain and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[353] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal had such a system, it ignored the results.

798. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert.

---

[352] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aca2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.2f757833e3c4; Lenny Bernstein & Scott Higham, *Investigations: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASHINGTON POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.7007bf2b9455; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL (Feb. 18, 2017), https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

[353] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.a5f051722a7a.

799. Meanwhile, the opioid epidemic rages unabated in the United States and Mississippi.

800. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

801. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' allegations of Defendants' unlawful acts below.

802. The Distributor Defendants have abandoned their duties imposed under Mississippi law, taken advantage of a lack of adequate law enforcement, and abused the privilege of distributing controlled substances.

IV. The National Retail Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids

803. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids.[354] They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

[354] Plaintiffs' allegations of wrongdoing are pointing to the National Retail Pharmacies not the pharmacy industry who in general serve a vital healthcare function in the United States.

804. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids.

805. Data shows that the National Retail Pharmacies distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in Mississippi. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Mississippi. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

806. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Mississippi in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided Defendants with data regarding, inter alia, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion, but failed to do so.

A. The National Retail Pharmacies Have a Duty to Prevent Diversion

807. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

808. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under Mississippi law. Pharmacy registrants are required to ensure that opioid prescriptions filled by them are written for a legitimate patient for a legitimate medical need in the usual course of practice for the prescriber. *See* Miss. Code Ann. § 41-29-137(f). In addition,

"[p]ersons registered to manufacture, distribute or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the [State licensing boards] may issue." Miss. Code Ann. § 41-29-133. Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

809. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

810. Suspicious pharmacy orders include orders unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

811. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

812. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

813. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

814. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

815. Despite their legal obligations as registrants under state law, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly. They knew they made money by filling prescriptions, not by not filling descriptions. They knew they made money by making it easy for doctors to refer patients with drug prescriptions to them to fill, not by making it difficult for doctors to refer patients to them to fill descriptions.

816. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. For instance, under CVS's Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

817. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that this problem was compounded by the National Retail

Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

818. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

819. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

820. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that

should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

821. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

822. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

B. Multiple Enforcement Actions Against the National Retail Pharmacies Confirm their Compliance Failures.

823. The National Retail Pharmacies have long been on notice of their failure to abide by the law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

1. CVS

824. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million

customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

825. CVS is a repeat offender; the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the law.

826. As recently as March 2019, CVS entered into a $535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island regarding allegations that its pharmacies in Rhode Island violated federal law "including by… in 39 instances between September 9, 2015 and June 18, 2017, filling a prescription for a Schedule II drug under circumstances … that the CVS pharmacist filling the prescription knew or had reason to know that the prescription in question was invalid or unauthorized…"

827. This fine was preceded by numerous others throughout the county.

828. In July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.[355]

829. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.[356]

---

[355] Press Release, U.S. Attorney's Office E. Dist. of Cal., CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act, U.S. Dep't of Just. (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violationscontrolled-substance-act.

830. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.[357]

831. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.[358]

832. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.[359]

833. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally

---

[356] Press Release, U.S. Attorney's Office Dist. of Md., United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances, U.S. Dep't of Just. (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-millionsettlement-agreement-cvs-unlawful-distribution-controlled.

[357] Press Release, U.S. Attorney's Office Dist. of Conn., CVS Pharmacy Pays $600,000 to Settle Controlled Substances Act Allegations, U.S. Dep't of Just. (Oct. 20, 2016), https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-actallegations.

[358] Dialynn Dwyer, *CVS will pay $795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), https://www.boston.com/news/localnews/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-inagreement-with-state.

[359] Press Release, U.S. Attorney's Office Dist. of Mass., CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions, U.S. Dep't of Just. (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filledfake-prescriptions.

permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.[360]

834. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."[361]

835. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.[362]

836. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.[363]

837. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.[364]

---

[360] Press Release, U.S. Attorney's Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved With $450,000 Civil Settlement, U.S. Dep't of Just. (Aug. 10, 2015), https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved- 450000-civil-settlement.

[361] Press Release, U.S. Attorney's Office M. Dist. of Fla., United States Reaches $22 Million Settlement Agreement with CVS For Unlawful Distribution of Controlled Substances, U.S. Dep't of Just. (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22- million-settlement-agreement-cvs-unlawful-distribution.

[362] Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News (Sept. 5, 2014), http://www.expressnews.com/business/local/article/H-E-BCVSfined-over-prescriptions-5736554.php.

[363] Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NEWSOK (May 3, 2015), http://newsok.com/article/5415840.

2. Walgreens

838. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

839. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.[365]

840. As part of the settlement, Walgreens admitted that it failed to uphold its obligations as a DEA registrant regarding the above-described conduct.[366]

841. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

842. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each

---

[364] Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay $11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act, U.S. Dep't of Just. (Apr. 3, 2013), https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penaltyclaims-involving-violations-controlled.

[365] Press Release, U.S. Attorney's Office S. Dist. of Fla., Walgreens Agrees to Pay a Record Settlement of $80 Million for Civil Penalties Under the Controlled Substances Act, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-recordsettlement-80-million-civil-penalties-under-controlled.

[366] *Id.*

allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.[367]

843. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens' corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the law or the health of communities.[368]

844. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold

[367] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).
[368] *Id.*

almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[369]

845. The six retail pharmacies in Florida that received the suspicious drug shipments from the Jupiter Distribution Center, in turn, filled customer prescriptions that they knew or should have known were not for legitimate medical use.[370]

846. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).[371]

847. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

848. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[372]

3. Rite Aid

849. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than $21 billion.

---

[369] *Id.*
[370] *Id.*
[371] Felice J. Freyer, *Walgreens to pay $200,000 settlement for lapses with opioids*, BOSTON GLOBE, Jan. 18, 2017, https://www.bostonglobe.com/metro/2017/01/18/walgreens-agrees-better-monitor-opioid-dispensing/q0B3FbMo2k3wPt4hvmTQrM/story.html.
[372] *Id.*

850. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA.[373]

851. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R 1301.76(b).[374]

852. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

853. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

854. Throughout the country and in Mississippi in particular, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

---

[373] Press Release, Dep't of Justice, Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act, U.S. Dep't of Just. (Jan. 12, 2009), https://www.justice.gov/opa/pr/rite-aid-corporation-andsubsidiaries-agree-pay-5-million-civil-penalties-resolve-violations.

[374] *Id.*

855. On information and belief, from the catbird seat of their retail pharmacy operations, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into Mississippi and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

856. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

857. On information and belief, because of (among others sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

858. The National Retail Pharmacies' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM AND SUBSTANTIAL DAMAGE ALLEGED HEREIN

859. As the Marketing Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the United States, including

Mississippi. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids.

860. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[375]

861. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[376]

862. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[377]

863. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.[378]

864. For example, one doctor in Ohio was convicted of illegally distributing some 30,000 tablets of oxycodone, OxyContin, and Opana. In connection with sentencing, the U.S. Attorney explained that its enforcement efforts reflected that "[o]ur region is awash in opioids that have brought heartbreak and suffering to countless families." Henry Schein delivered opioids directly to the office of this doctor, whom the Northern District of Ohio court has described as "selling 30,000 doses of poison into the community."[379] In a separate civil suit, the same prescriber reached a consent judgment alleging that he was purchasing hydrocodone/APAP

---

[375] *See* Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241-248 (2015), doi: 10.1056/NEJMsa1406143, http://www.nejm.org/doi/full/10.1056/NEJMsa1406143.

[376] *See* Volkow & McLellan, *supra* n. 84.

[377] *See* Califf et al., *supra* n. 29.

[378] *See* Press Release, Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra* n. 78.

[379] Eric Heisig, *Former Akron-Area Doctor Sentenced to 63 Months in Prison for Doling Out Painkillers*, Cleveland.com (Mar. 16, 2015), https://www.cleveland.com/court-justice/index.ssf/2015/03/former_akron-area_doctor_sente.html.

tablets (hydrocodone and acetaminophen), from Henry Schein on as many as fourteen separate dates within a one-year period, and, subsequently dispensed 11,500 hydrocodone tablets without maintaining purchase and dispensing records as required by the CSA.

865. As shown above, the opioid epidemic has escalated with devastating effects: substantial opiate-related substance abuse, hospitalization, and death that goes hand in hand with Defendants' increased distribution of opioids.

866. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids by Defendants has caused the opioid epidemic to include heroin addiction, abuse, and death.

867. Defendants repeatedly and purposefully breached their duties under federal and Mississippi law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes and the foreseeable, inevitable financial burdens imposed on and incurred by hospitals and other health care providers.

868. Hospitals are integral to the solution to the opioid epidemic, because they can "aid in the proper treatment of postoperative pain while also helping to combat a nationwide epidemic."[380] Indeed, "*[h]ospital* pharmacists…are in an ideal position to help address the opioid epidemic and make sure these agents are used appropriately."[381] But Defendants' wrongful conduct has jeopardized the ability of Plaintiffs and other hospital purchasers to properly limit their purchasing and dispensing of opioids, particularly at the key junctures of patient admission and discharge. Indeed, by creating and fueling the opioid epidemic,

[380] Opioid Exit Plan, *supra* n. 155.
[381] Joey Sweeney, *Hospital Pharmacists Can Help Reduce Opioid Prescriptions*, PHARMACY TODAY (July 2016) (emphasis added), *available at* https://www.pharmacytoday.org/article/S1042-0991(16)30505-9/fulltext.

Defendants have impaired the hospitals' ability to perform their integral responsibilities to patients.

869. During admission, hospital professionals routinely consult with the patient to assess which medications the patient is taking at home. But, due to Defendants' conduct, hospitals can no longer trust patients to self-report their prescriptions. Hospital pharmacists may also check available databases to ensure that patients are not stockpiling prescription opioids, but such databases often do not record the actual flow of opioids.[382] Hospital pharmacies' inability to rely on their patients' self-reporting, and having to take additional steps to independently verify their patients' purchases from other sources, imposes additional burdens on hospitals.

870. Then, before discharge, hospital professionals "obtain a list of planned outpatient prescriptions and perform a counseling session on how to safely and effectively control postoperative pain."[383] The hospitals' efforts to provide meaningful counseling is subverted by Defendants' sales practices described in the Complaint, pursuant to which Defendants have disseminated misinformation throughout all levels of the marketplace and fostered increased demand for their products.

871. Hospitals must admit opioid users who present in need of intensive care or who display symptoms of mental illness. Defendants knew that federal and state law require hospitals to admit and treat opioid-addicted patients. Similarly, if a pregnant opioid addict presents for treatment, the Hospital must provide care for both the opioid-addicted mother and the opioid-addicted baby. Defendants relied on Plaintiffs to provide a safety net to prevent overdose deaths and treat health consequences arising from opioid addictions and depended on hospitals

[382] *Id.* at ¶ 32.
[383] Opioid Exit Plan, *supra* n. 155.

themselves to mitigate the health consequences of their illegal activities.[384] In 2011, it is "estimated that [there were] greater than 420[,000 emergency room] visits related to the misuse of abuse of narcotic pain relievers" in the United States.[385] Hospitals bear an enormous burden in providing care, as insurance covers only a portion of the cost.

872. The increased financial burdens on hospitals include, but are not limited to the following:

a) Unreimbursed costs for providing healthcare and medical care, additional diagnostic, therapeutic and other treatments for patients suffering from opioid-related addiction or disease, including physical and mental disabilities, overdoses and deaths.;

b) Costs associated with patient counseling with respect to pain management, necessitated by overprescription to the general population and dissemination of false and misleading information to prospective patients and others; as hospitals and other providers question their patients' self-reporting, it necessitates further steps to be taken in all phases of treatment and counseling;

c) Unreimbursed costs of opioids purchased by hospitals themselves, which were direct targets of the Defendants' marketing campaigns;

d) Unreimbursed costs of prescription drugs used to treat addiction;

e) Costs of training additional personnel in the proper treatment of drug overdoses;

f) Costs associated with obtaining and training staff in the application of naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

g) Additional unreimbursed costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families; and

h) Unreimbursed Costs for providing treatment of infants born with opioid-

[384] *Id.* at ¶ 19.
[385] Cindy Williams, Vice President and Chief Pharmacy Officer, Riverside Health System, *Establishment of an Opioid Stewardship Program*, *available at* http://www.vshp.org/uploads/6/3/6/0/6360223/williams-opioid_1_per_page.pdf (hereinafter described as the "Va. Hospital Pharmacists Paper").

related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy.

873. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harm to Plaintiffs.

874. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief.

TOLLING AND FRAUDULENT CONCEALMENT

875. Defendants, individually and acting through their employees and agents, knowingly and intentionally concealed material facts and knowledge from Plaintiffs and others to induce them to purchase and administer opioids as set forth in detail above.

876. The Defendants invented the term "pseudoaddiction" and promoted it to the medical community, including Plaintiffs. Defendants provided the medical community, including Plaintiffs, with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales.

877. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addition and death; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; in falsely portraying their efforts or commitment to rein in the supply and diversion of opioids; and doing all of this while knowing full well that their statements were

misrepresentations of facts material, Defendants have engaged in intentional, fraudulent misrepresentations and concealment of the material fact, as detailed herein.

878. Defendants intended that Plaintiffs would rely on their misrepresentations, omissions, and concealment, knew that Plaintiffs would rely on their misrepresentations, and that such reliance would cause harm to Plaintiffs. The medical community, including Plaintiffs, were duped by the Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in Mississippi.

879. Plaintiffs reasonably relied on Defendants' misrepresentations and omissions in writing and filling prescriptions for Defendants' opioids. The use of Defendants' opioid medicines became widespread and continuous as a result.

880. The continued tortious and unlawful conduct by the Defendants caused a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The nuisance created by Defendants remains unabated.

881. Plaintiffs' claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts and their wrongful acts, and the material information pertinent to their discovery, which Defendants concealed from the Plaintiffs. Plaintiffs did not know, or could not have known through the exercise of reasonable diligence, of their claims, as a result of Defendants' conduct.

882. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their

conduct. As a result of the above, Plaintiffs were unable to obtain vital information bearing on their claims absent any fault or lack of diligence on their part.

883. Plaintiffs seek restitution resulting from the unlawful acts of Defendants for the increased costs of care to patients suffering from opioid-related conditions. They do not seek damages which may have been suffered by individual citizens for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

884. Plaintiffs were injured, and Defendants unjustly enriched by Defendants concealment of material facts. These injuries include but are not limited to, expending funds on emergency services, emergency response, additional training, additional security, and other services Plaintiffs would not have incurred.

885. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a hospital would reasonably expect to occur and is not part of the normal and expected costs of a hospital's existence. Plaintiffs allege wrongful acts which were neither discrete nor of the sort a hospital can reasonably expect.

WAIVER OF CERTAIN CLAIMS FOR RELIEF

886. Plaintiffs expressly disclaim and waive any and all right to recovery, whether financial, injunctive, or equitable, relating to or arising out of the distribution by any person of any product, or the provision of any service, pursuant to McKesson Corporation's Pharmaceutical Prime Vendor Contract with the United States Department of Veteran Affairs ("PVV Contract"). Plaintiffs further commit that they will not, in any forum, rely on or raise the PPV Contract in connection with their allegations and/or prosecution in this matter.

887. Plaintiffs agree that should Defendants present evidence sufficient for the trier of fact to determine that Plaintiffs' injuries were caused, in whole or in part, by the distribution of products or provision of services through the PPV, Defendants are entitled to a reduction of their liability proportionately by the extent to which the trier of fact determines that any injury to Plaintiffs was caused by goods or products distributed and/or services provided through the PPV.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Restitution/Unjust Enrichment
(Against All Defendants)

888. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

889. This claim is brought under the common law of unjust enrichment.

890. Plaintiffs provided unreimbursed healthcare treatment to patients with opioid related conditions that Defendants are responsible for creating. Plaintiffs thereby conferred a benefit on Defendants because Defendants should bear the expense of treating these patients' opioid conditions. This is because Defendants created the opioid epidemic and the patients' opioid conditions, as described above.

891. Defendants appreciated and knew of this benefit because they knew their opioid promotional and marketing policies would cause, and in fact have caused, hospitals throughout the United States and Mississippi to provide unreimbursed healthcare treatment to patients with opioid related conditions that Defendants were responsible for creating.

892. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the opioid epidemic.

893. Plaintiffs purchased and continue to purchase opioid products marketed and sold by Defendants. Defendants directly marketed their opioid products through false, deceptive, and unfair marketing of opioid products purchased by Plaintiffs, their pharmacy representatives, and their doctors.

894. Defendants have received and continue to receive the benefit of the false, deceptive, and unfair marketing and sales of their opioid products directly to Plaintiffs, their pharmacy representatives, and their doctors.

895. The circumstances under which Defendants accepted or retained the benefit, described above, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

896. As described above, the benefit was received and retained under such circumstances that it would be inequitable and unconscionable to permit Defendants to avoid payment therefor.

897. Defendants have therefore been unjustly enriched at the expense of Plaintiffs.

898. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to the Plaintiffs.

SECOND CLAIM FOR RELIEF
Indemnity
(Against All Defendants)

899. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

900. As a direct and proximate result of Defendants' actions as alleged above, Plaintiffs were obligated by law to pay and have paid millions of dollars in the past for the

provision of necessary medical care, facilities and services for those suffering from opioid-related conditions.

901. Additionally, Plaintiffs purchased and continue to purchase and administer opioids marketed and sold by Defendants. Defendants directly marketed their opioid products to Plaintiffs through their false narrative. Plaintiffs are direct customers and victims of Defendants' false, deceptive, and unfair marketing of opioids.

902. In all fairness and justice and to prevent an unjust enrichment, Defendants should indemnify Plaintiffs for the provision of necessary medical care, facilities and services for treatment of patients with opioid related conditions and for reimbursement of the costs expended by Plaintiffs in purchasing opioids from Defendants as a result of their false narrative.

THIRD CLAIM FOR RELIEF
Nuisance
(Against All Defendants)

903. Plaintiffs repeat, reallege, and incorporate by reference all other paragraphs of this Complaint, as if fully set forth herein.

904. This action is brought by Plaintiffs to abate the nuisance created by Defendants.

905. The nuisance created by Defendants is the over-saturation of opioids in the patient population of Plaintiffs and in the geographic area served by Plaintiffs for illegitimate purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

906. Defendants, individually and acting through their employees and agents, through fraudulent and deceptive marketing and other fraudulent schemes as described herein, created and maintained the opioid epidemic in Plaintiffs' communities, which is harmful and disruptive

to and substantially and unreasonable annoys, injuriously affects, endangers, and interferes with the safety, health, morals, comfort, and general welfare of the public.

907. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiffs, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

908. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

909. Defendants' activities unreasonably interfere with Plaintiffs' economic rights and the reasonable use of Plaintiffs' property. Plaintiffs' resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resources which could be used to benefit the community within the geographic area served by Plaintiffs as well as other health care areas.

910. The Defendants' interference with these rights of Plaintiffs is unreasonable because it:

a. Has harmed and will continue to harm the public health services of and public peace of Plaintiffs;

b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiffs serve;

c. Is proscribed by statutes and regulation, including the CSA and KCPA;

d. Is of a continuing nature and it has produced long-lasting effects;

e. Was the result of conduct that the Defendants knew, or had reason to know, would inflict a significant effect upon Plaintiffs; and

f. Has inflicted substantial costs on Plaintiffs.

911. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

912. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid addiction and failing to identify, halt, and report suspicious opioid transactions.

913. Defendants knew of the public health hazard their conduct would create. It was foreseeable to Defendants that their conduct would unreasonably interfere with the ordinary comfort, use, and enjoyment of residents within the State of Mississippi.

914. Defendants' conduct is unreasonable, intentional, unlawful, reckless, and/or negligent.

915. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Supply Chain Defendants had the power to shut off the supply of illicit opioids to Plaintiffs and in the geographic areas served by Plaintiffs.

916. As a direct and proximate result of the nuisance, Plaintiffs have sustained economic harm by spending a substantial amount of money trying to remedy the harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services and healthcare. In short, the Defendants created a mess, leaving to the Plaintiffs and other hospitals the costs of cleaning it up. This is a classic nuisance.

917. As a result of Defendants' actions, Plaintiffs have suffered a special injury, different from that suffered by the public at large by individual users and by governmental

entities, namely that Plaintiffs have provided uncompensated care for patients suffering from opioid-related conditions and incurred elevated operational costs.

918. The public nuisance – i.e. the opioid epidemic – created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

919. Defendants should be required to pay the expenses Plaintiffs have incurred or will incur in the future to fully abate the nuisance.

920. The Purdue Individual Defendants directed and participated in the tortious conduct of Purdue and are individually liable.

921. Therefore, Plaintiffs demand judgment in their favor against the Defendants for injunctive relief, abatement of the public nuisance, and for damages in an amount to be determined by a jury, together with all cost of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that the Court:

A. That the acts alleged herein be adjudged and decreed to be unlawful in violation of State common law;

B. That Plaintiff recover the all measures of equitable relief allowable under the state common law, and that judgment be entered against Defendants in favor of Plaintiff;

C. That Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, investigative costs, and reasonable attorneys' fees as provided by law;

D. That Defendants be ordered to pay restitution to Plaintiff;

E. That Defendants be ordered to abate the nuisance that they created in violation of State law; and

F. That the Court order such other and further relief as the Court deems just, necessary and appropriate.

Dated: October 16, 2019.

Respectfully Submitted,

John W. ("Don") Barrett (MSB # 2063)
David McMullan, Jr. (MSB # 8494
Richard Barrett (MSB # 99108)
Sterling Starns (MSB # 104277
BARRETT LAW GROUP, P.A.
P.O. Box 927
404 Court Square North
Lexington, MS 39095
Tel: (662) 834-2488
Fax: (662) 834-2628

Michael L. Fondren (MSB # 8941)
CITRIN LAW FIRM
P.O. Box 2187
Daphne, Alabama 36526
Email: Michael@citrinlaw.com
Tel: (228) 888-8822

Steve Martino
Lloyd Copeland
Ruth R. Lichtenfeld
TAYLOR MARTINO, P.C.
455 Saint Louis Street, Suite 2100
P.O. Box 894
Mobile, Alabama 36601
Tel: (251) 433-3131

Jonathan W. Cuneo
Monica Miller
Mark H. Dubester
David L. Black
Jennifer E. Kelly
Evelyn Li
CUNEO GILBERT & LADUCA, LLP
4725 Wisconsin Avenue, NW, Suite 200
Washington, DC 20016
Tel: (202)789-3960

J. Kirkham Povall

S. Todd Jeffreys
POVALL & JEFFREYS PA
215 North Pearman Avenue
P.O. Box 1199
Cleveland, MS 38732
Tel: (662) 843-9957

Warren Burns
BURNS CHAREST, LLP
900 Jackson St., Suite 500
Dallas, Texas 75202
Tel: (469) 904-4550
Fax: (469) 444-5002

Korey A. Nelson
Lydia A. Wright
Rick Yelton
BURNS CHAREST, LLP
365 Canal Street, Suite 1170
New Orleans, LA 70130
Tel: (504) 799-2845
Fax: (504) 881-1765

Gerald M. Abdalla, Jr.
ABDALLA LAW, PLLC
602 Steed Road, Suite 200
Ridgeland, Mississippi 39157
Tel: (601) 487-4590

Gerald J. Diaz, Jr. (MSB # 6063)
Christopher P. Williams (MSB # 10774)
James R. Segars, III (MSB # 103605)
THE DIAZ LAW FIRM, PLLC
208 Waterford Square, Suite 300
Madison, MS 39110
Phone: (601) 607-3456
Fax: (601) 607-3393

Attorneys for Plaintiffs